

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
vs.)
)
AARON MICHAEL SHAMO,) Case No: 2:16CR00631
)
Defendant,)
)
_____)
)
)

BEFORE THE HONORABLE DALE A. KIMBALL

August 22, 2019

JURY TRIAL

PAGES

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1 SALT LAKE CITY, UTAH, THURSDAY, AUGUST 22, 2019

2 * * * * *

3 THE COURT: Are we ready to proceed?

4 MR. SKORDAS: Yes.

5 THE COURT: We'll get the jury and proceed.

6 (Whereupon, the jury returned to the
7 court proceedings.)

8 THE COURT: Good morning. Welcome again. Thank
9 you for your work.

10 The government may call its next witness.

11 MR. BURGGRAAF: United States would call
12 Frank Platek.

13 THE COURT: Come forward and be sworn, please.

14 THE CLERK: Please raise your right hand.

15 STANLEY FRANK PLATEK,
16 called as a witness at the request of Plaintiff,
17 having been first duly sworn, was examined
18 and testified as follows:

19 THE WITNESS: I do.

20 THE CLERK: Please come around to the witness box.
21 Please state your name and spell it for the record.

22 THE WITNESS: Yes. Stanley Frank Platek.

23 S-T-A-N-L-E-Y F-R-A-N-K, Platek is P-L-A-T-E-K.

24 //

25 //

1 DIRECT EXAMINATION

2 BY MR. BURGGRAAF:

3 Q. Mr. Platek, thanks for being here this morning. As
4 you are aware I sometimes pronounce things incorrectly, and
5 you feel free to correct me if I do.

6 Can you tell me your current occupation is and
7 where you're employed?

8 A. Yes. I'm employed with the US Food and Drug
9 Administration's Forensic Chemistry Center as a biologist in
10 the trace evidence section.

11 Q. And how long have you been employed by the FDA?

12 A. I've been employed by the FDA for over 28 years.

13 Q. And in your current positions what are your job
14 responsibilities?

15 A. Mostly to handle anything related to tampering,
16 particle analysis and to be a lead analyst when so designated
17 for any type of samples that come in related to my areas of
18 expertise.

19 Q. And what's your educational background?

20 A. I have a Bachelor of Science degree from Murray
21 State University in biology with a minor in chemistry. I have
22 a Master of Science degree in Industrial Hygiene from the
23 University of Cincinnati College of Medicine.

24 Q. What additional training do you have that relates
25 to your current position with the FDA?

1 A. I have had numerous courses and training classes
2 throughout my career with the government of over 43 years. I
3 have several courses in toolmark examination, a two-week
4 course with the Indiana State Police and a one-week course
5 with the safety institute of Ohio's Department of Justice
6 operation, in which they instructed the full analysis of
7 toolmarks.

8 Q. And do you provide training to others?

9 A. Yes. I provide training in a number of other
10 areas. I've been a faculty instructor at Northern Kentucky
11 University in northern Kentucky since 1982. And I teach
12 scanning electron microscopy and energy-dispersive x-ray on
13 microanalysis. I also teach at the Lehi University Microscopy
14 School, and I've been doing that since 2005.

15 Q. And what professional organizations do you belong
16 to?

17 A. I'm a member of the academy -- American Academy of
18 Forensic Scientists. I am a member of the Midwestern
19 Association of Forensic Scientists. I'm a member of the Ohio
20 Valley Microscopy Society, and I'm also a member of the
21 Microscopy Society of America, in which three years ago I was
22 honored as a fellow of that society.

23 Q. And have you testified as an expert before?

24 A. I have.

25 Q. How many times?

1 A. Three times. State and federal.

2 Q. And has the Court ever made a finding that your
3 testing methods or results were not accurate or correct?

4 A. No, sir. That is correct.

5 Q. Have you had any experience analyzing pill press
6 punches and dies?

7 A. I have.

8 Q. What did you do to prepare for your testimony
9 today?

10 A. Reviewed my notes, thought about the manner in
11 which I would present. But normally it would just be review
12 what I've done and how I put my worksheets together.

13 Q. And you've had a couple of less than full nights of
14 sleep, as well.

15 A. That's true.

16 Q. Okay. Let's speak more generally -- first, how did
17 you become involved in this case?

18 A. The case was assigned to me by our supervisor from
19 the trace evidence section. We rotate how often different
20 people take positions as a lead analyst in a case, and for
21 this particular one since it would need an initial microscopy
22 front end and some of the additional physical examinations I
23 was assigned to take the sample.

24 The sample was picked up from our sample custodian
25 in the laboratory where I signed for it to maintain chain of

1 custody. I take it to our laboratory. And at that point the
2 sample is -- we have several forms that we put together that
3 are part of our procedure for bringing new samples into the
4 laboratory. And we take those. Those were prepared. We
5 identify the seals, and then we go through a full photo
6 documentation of each of the items as received. We don't open
7 anything. Everything is photo documented.

8 And at that point we will be getting information
9 from both the information provided by the special agent as to
10 what their request was for analyses. They will also -- in
11 conference we take a look at what the evidence may be, say, we
12 might suggest we could do this. They say, we would like this.
13 We may not be able to perform some of those with what's
14 provided or we might need more information. So we will be in
15 contact with the special agent or submitting agents in these
16 cases.

17 And at that point we decide -- it's sort of a
18 triage as to how a sample is going to be addressed. If you're
19 going to do a destructive technique on something you can't do
20 that destructive technique first and then take it on and hope
21 to do something else. So we decide who is going to receive
22 which portions of a sample and for what reasons.

23 Q. I want to kind of backup just a little bit as far
24 as speaking more generally about the FDA lab, which I'm
25 referencing as the FDA lab the forensic chemistry center.

1 A. Correct.

2 Q. First of all, is the lab a certified or national
3 accredited lab?

4 A. We are. We are an accredited forensic laboratory.
5 We are accredited through a group that's all A-NAB and the
6 ANAB. And the A in ANAB stands for the American National
7 International -- I'm sorry. We converted about a year and a
8 half ago. The American National Institute of Standards. And
9 then the NAB part is National Accreditation Board.

10 Q. I'm not going to ask you for every specific
11 requirement. But what's typically required to become an
12 accredited lab?

13 A. Obviously having a secure forensic security with
14 full chain of custody from time in to time out. We have
15 procedures in place for all instrumentation. We have analysts
16 that are determined through testing to be proficient in the
17 disciplines in which they are working. We get annual tests in
18 specific disciplines based upon what we are doing in the
19 laboratory. And it's a -- some of them are very rigorous, and
20 you must pass it to go on. They are ways to handle it if
21 there are issues with that. There have not been problems
22 along those areas.

23 We also have to have a facility set up in such a
24 manner that the analyses can be performed in a safe fashion
25 under safe working conditions. The sample security is very

1 high priority with us. And there are a number of other ones
2 as far as procedures, how you handle things, at the ANAB rules
3 and regulations, as it is with any forensic accreditation
4 board are very stringent. And it takes truly years to be
5 prepared to be ready for one.

6 Q. What types of equipment or instrumentation is
7 utilized at the lab?

8 A. We have -- with all bragging rights among
9 scientists, we have an incredible array of instrumentation in
10 our laboratory. For the microscopy side we have almost every
11 type that is available. I say almost. We have everything
12 from your basic light microscopes to scanning electron
13 microscopes. We are equipped with all types of spectrometers.
14 We have infrared analysis instrumentation. We have gas
15 chromatography, mass spectrometers, we have inductively
16 coupled plasma emissions spectrometer used for analyzing for
17 elements. There are a lot of these different types of
18 instruments in the laboratory, and that doesn't begin to touch
19 them all. A lot of these we have in duplicate and triplicate
20 because of the fruit put through the laboratory and what we
21 do. You need to have a lot of instruments.

22 All instruments are certified. We also have a
23 procedure in which if an analyst is going to use that
24 instrument that day they must perform a performance validation
25 of that instrument. You can't assume that it's going to work

1 properly. And every day if you're going to use it you have to
2 log in onto it, you have to perform the test with a certified
3 standard, whether it's chemical or physical. It's recorded in
4 two places, one in the logbook right at the instrument, and
5 one goes on to our quality assurance folder which is on the
6 laboratory server. And again, once it goes in it cannot go
7 out.

8 Q. Is there standard policies and protocols for
9 ensuring that the instrumentation and equipment is properly
10 sterilized?

11 A. Sterilized, we do not do sterilization with the
12 exception of our biological safety laboratory 3. We have a
13 full BSL 3 laboratory at the forensic chemistry center, and
14 that's handled for the microbiologist.

15 But as far as cleaning, preparation, making sure
16 that the samples are used, absolutely, that the surfaces are
17 wiped. I will exchange backing papers between samples to
18 prevent cross-contaminations, just as an example.

19 Q. Now, you mentioned quite a few protocols and
20 policies in how the lab operates. As the lead analyst and to
21 your knowledge were those policies and protocols followed in
22 the analysis in this case?

23 A. To the best of my knowledge, yes.

24 Q. Are the processes and tests and methods for
25 analyzing items in the lab commonly accepted and considered

1 reliable in the scientific community?

2 A. They are, yes, sir.

3 Q. While using the lab equipment to analyze and exam
4 items in the case did you have any indication that any
5 equipment was not operating properly?

6 A. No, sir.

7 Q. Are the labs results found by one analyst confirmed
8 by another?

9 A. They are definitely confirmed. Every analyst who
10 is assigned a portion of the sample to analyze will perform
11 their analyses. They will prepare a worksheet section, and it
12 will be called an analytical section. They will perform that
13 section, and that section is not only checked but fully
14 reviewed by another member of the forensic chemistry center
15 who is proficient in that technique. You want to have
16 somebody who knows what you're doing review your work. And
17 they'll make sure that everything both scientifically is
18 correct, that your calculations are correct, every single one
19 of them, and that, quite honestly, the right form is used.
20 All analytic information is in there. We do have SOPs on
21 that, as well.

22 Q. What does SOPs stand for?

23 A. Standard operating procedure.

24 Q. Okay. Let's get a little more in-depth in this
25 specific case. You mentioned retrieving items as well as a

1 request after being assigned as the lead analyst in this
2 matter.

3 A. Correct.

4 Q. What items specifically -- how are the items
5 labeled that were requested to be analyzed?

6 A. I received 22 items, and they were each in
7 individual evidence bags, sealed evidence bags. One side of
8 the evidence bag had a DEA label, evidence label on it, the
9 opposite side had an OCI, our office of criminal investigation
10 label. Each bag also had a tape over the seal end with the
11 FDA OCI number information on it, as well. And all bags were
12 sealed, received sealed.

13 Q. Now you referenced a DEA label on the front of it.
14 I would like to approach and present you with Government's
15 Exhibit -- let me make sure I've got the right number here --
16 7.43.

17 Now, I'm not going to ask if you recognize that
18 specific exhibit. But the label on the front of that, does
19 that look similar to the DEA labels that were on the 22 items
20 that were received?

21 A. It does. Including the one on the vial that's
22 inside here.

23 Q. And the labels that were on the 22 items that you
24 received similar to this label, did it have a DEA exhibit
25 number listed?

1 A. Yes, it did. On this -- just like this one right
2 here.

3 Q. Okay. Thank you.

4 In preparation for your testimony did you take the
5 time to list out essentially what the items were that were
6 received and the general categories?

7 A. I did.

8 Q. Did you do so on that white pad?

9 A. I did. In advance of this I prepared for easier
10 demonstration.

11 If I may get up, Your Honor?

12 THE COURT: You may as long as you speak up.

13 MR. BURGGRAAF: And, Your Honor, I believe he's
14 going to stay in his seat. He is just going to flip the paper
15 over so the jury can see how he listed it out.

16 THE COURT: Okay.

17 Q. BY MR. BURGGRAAF: Can you explain to the jury what
18 it is they're looking at there that you listed?

19 A. Yes. If you take a look at this, on the very top
20 line it says, Items 1 through 5, 7, and 11 were all tablets in
21 which the debossing on the tablets, the marks that are down
22 into the surface of the tablet, had the A and 215. It also
23 had a half score on this.

24 The next lines down is Items 6, 8, 9, 10, 12 and
25 13, and those were debossed with a capital M that is enclosed

1 within a square, and the square has slightly rounded edges,
2 and the number 30 on the opposite side with a half score.

3 The next line down is Items 14 through 19. And
4 these were oblong tablets that were marked GG249 on one side
5 with three, what we call, quarter scores. There were three
6 separate marks on there. And the backside of that tablet had
7 nothing on it.

8 The next one is Item 20. There were two tablet
9 punches in there that were also marked with the GG249. Now
10 these were embossed. It's a negative image of what would have
11 been on the tablet. And they were embossed with the GG249.
12 Included with that were other tablet punch tips, et cetera,
13 even five tablet dies. And dies are another part of the
14 tableting process that were included with that sample.

15 The Item 21, there were 9 punches that had the
16 M, capital M with the square with the rounded corners. And
17 tablet -- or Item 22 were 8, again more tablet punches, and
18 these were all with the embossing GG249.

19 Q. So the last three items contained punch or punch
20 tips.

21 A. Right. The punches with the tip on the end of it,
22 correct.

23 Q. Now you mentioned Item 20 that there were two punch
24 tips with the GG249. You've got it separate there. Why
25 haven't you listed out the additional punches?

1 A. The reason we have not listed the other ones here
2 is we did not have corresponding tablets for comparison for
3 any of the other punch tips that were included with that
4 sample.

5 Q. I want to start with Items 1 through 5, 7 and 11.
6 You've got it listed that they were each debossed with A215.
7 In each of the items both on that first line and the next two
8 that reference pills or tablets, how many of those pills or
9 tablets were in each item?

10 A. Each item came with five tablets for all Items 1
11 through 19.

12 Q. And do you know where those tablets came from
13 before being at the FDA lab?

14 A. No, I was not. I was told they would be coming
15 from DEA when we saw the evidence, but that was the extent of
16 it.

17 Q. So the first line you've got the debossed tablets
18 with A215. Do you know what the A215 means in the
19 pharmaceutical world?

20 A. In the pharmaceutical world this one would refer to
21 an Oxycodone tablet.

22 Q. And the next line down, the M or M box with the 30,
23 do you know what that --

24 A. That's also an Oxycodone embossment.

25 Q. And the GG249, do you know what that signifies?

1 A. Yes. Alprazolam.

2 Q. So as the lead analyst in respect to the requested
3 analysis, what was your role?

4 A. My role as lead analyst in this one was as I
5 mentioned before to evaluate the sample as I first receive it,
6 document how I first received it, and then I will upon
7 deciding once we've talked with other analysts and other
8 supervisors how they want us to approach the analyses on
9 these, I would open the sample, and we have a protocol, we
10 will put our initials and a date and we will open it directly
11 on the bag, and then the samples were removed.

12 In the case of Items 1 through 19, those tablets
13 were received in small glass vials with a white top. And the
14 tablets were removed from those. So this was done in a fume
15 hood now because we weren't sure what we were dealing with.
16 And we would have a 50 millimeter, which is about 2 1/2 inches
17 in diameter petri dishes that have forcible lids. The hold
18 on. We use these a lot in the laboratory. They're new.
19 They're fresh. They're brand-new out of the package, and
20 they're sterile when we do receive them.

21 We open one of those up after labeling it, and then
22 the five tablets we put in there and put the seal. And then
23 all -- once that was done with all of the samples with their
24 own individual item petri dish were put into a plastic
25 snap lid container, and that was retained, and since we've

1 opened it in a hood.

2 Q. And is that container then labeled to ensure that
3 items stay separate and clearly identified?

4 A. Yes. Each one is individually identified within
5 there, yes, sir.

6 Q. So let me take you back just prior to this portion.
7 You mentioned and kind of confirmed that each of the items
8 came in a separate evidence bag; is that right?

9 A. Yes.

10 Q. And they had multiple labels on it?

11 A. Yes.

12 Q. I want to reference the DEA label that you
13 mentioned. You mentioned that it had the DEA exhibit number
14 listed.

15 A. (Witness indicates by nodding head up and down.)

16 Q. On Item 1, did that label have DEA Exhibit
17 Number 14 noted on it?

18 A. I would have to look in my records to confirm that
19 for Item 1.

20 Q. Did you note that -- did you note down what DEA --

21 A. The DEA numbers were not noted, but they are
22 captured for the photos for with each one of the items. It
23 will be on the bag.

24 Q. Okay.

25 A. And I do have that in my record in my Section 1.

1 Q. Okay. Section 1.

2 MR. BURGGRAAF: If I may approach?

3 THE COURT: You may.

4 THE WITNESS: Thank you.

5 Q. BY MR. BURGGRAAF: Mr. Platek, I think if you can
6 look at Item 1 and explain to the jury what DEA exhibit number
7 is listed.

8 A. Exhibit Number 14.

9 Q. And Item Number 2, what DEA exhibit number is
10 listed?

11 A. Item 34.

12 Q. And Item Number 3, which DEA number is listed?

13 A. I'm sorry. You're printed on both sides here.

14 Item 1 was 14; Item 2 was 34; Item 3 was 64; Item 4
15 was 123. Do you wish me to go on?

16 Q. Yes. Please go through Item 22.

17 A. Sure. Item 5 is 193; Item 6 is, it looks like 45.

18 Q. Is it possible that that's an 85?

19 A. The first character is slightly squiggled. Let me
20 take a look and see if I can look on a different portion of
21 that. Yes. If I look up on the yellow label it's 85.

22 Q. Okay.

23 A. And Item 7 appears to be 95; and Item 8 is, it
24 looks like they have it as Exhibit 85.02.

25 Q. Could that be 95.02?

1 A. That is hard to read. It could be a 95 on this
2 one. The yellow tag above it does have 95 for the exhibit on
3 it. I apologize.

4 Item 9 is 96; Item 10 is 136; Item 11 is 174;
5 Item 12 also has 174 on it; at least on their exhibits here;
6 Item 13, 188; Item 14, 54; Item 15 is Exhibit 15; Item 16 is
7 Exhibit 97; Item 17 is 126; Item 18, 173; Item 19, 185;
8 Item 20, 177; Item 21 is 178; and Item 22, 179.

9 Q. Now, the jury previously heard testimony about each
10 of these exhibits and several of them that were tested by the
11 DEA lab. The testimony for multiple items that you went over,
12 they heard testimony that was positive for the presence of
13 Fentanyl while others were positive for the presence of
14 Alprazolam.

15 When you documented those items in their evidence
16 bags did they have any sort of cautionary label?

17 A. Yes, sir. The first three appear on the Items 1
18 through 5 had a cautionary label on there that said Fentanyl.
19 Now, Items 1 through, I believe 1 through 13 had a caution
20 label on it. But they all did not necessarily have anything
21 else handwritten on them. The remainder of them, Items 14
22 through 19 did not have a caution on the bag.

23 Q. And Items 20, 21, 22, did they have any sort of
24 cautionary label?

25 A. Not to my recollection, no.

1 Q. What precautions -- seeing those precaution labels,
2 did you take any additional precautions on how the items are
3 handled?

4 A. We do. Whenever there's a concern of Fentanyl the
5 samples are handled in a fume hood. We'll keep them in that
6 area as much as possible while we're processing them. As I
7 mentioned when they were opened they were done in a fume hood.
8 The samples in the case of the tablets are kept in petri
9 dishes until they have to be opened, say, under a microscope
10 or whatever. And aside from that they're closed and retained
11 in the one area.

12 Q. Now, you mentioned after the items were removed
13 from the evidence bag that they were then photographed.

14 A. They were.

15 Q. What type of instrument was used for photographing
16 the items?

17 A. The initial one was done by stereoscopic light
18 microscopy. And I positioned three tablets trying to show at
19 least two with the debossing and one with the backside of the
20 tablet for verification.

21 Q. Can I abbreviate that by saying SLM?

22 A. SLM, that is correct.

23 Q. Because I'm probably going to get it wrong if I say
24 it otherwise.

25 What type of tool is this?

1 A. It's a microscope, and you've seen them on TV on
2 forensic files. It's a large binocular microscope that you
3 can look into. Very high-end lenses inside of those, glass
4 lenses. We can light below from underneath. We can project
5 lights on the top, and we even have cable arms and wands that
6 we can put fiberoptics directly onto the tablets or whatever
7 we're examining.

8 Q. And that's used to actually take the photographs?

9 A. We do. The system is also included with a very
10 high-end digital camera, which is located on the top of this
11 microscope. It makes it actually a safer way for us to do
12 this because we don't have to put our face where our eyes are
13 here and samples are here close to your face, we can put it
14 down here. We can be back from it and actually use a mouse
15 and a screen, and we can see exactly what we're going to
16 capture using a camera and capture those images. It's the
17 same way if you were putting a cell phone up there and
18 collecting those images on a large monitor.

19 Q. Let's look through a few of those photographs that
20 you took. If we can look at Government's Exhibit 24.01.

21 Is this one of the photos you took?

22 A. It is.

23 Q. And what is it depicting?

24 A. This is an image of three of the tablets of the
25 A215 type that you see on the top over here. And the two on

1 the right show the debossed surfaces with the half score that
2 I mentioned. The tab on the upper left is the same thing on
3 the other side. But this one is showing the backside of the
4 tablet to show there is nothing on the backside of that
5 tablet.

6 Q. Now you mentioned previously that in each item
7 there were five tablets. Why are there only three depicted in
8 this photo?

9 A. The lowest magnification that I can use on the
10 stereoscopic microscope and capture this type of image is
11 done, and that's the largest field I can get. If I tried to
12 put any more tablets into this field they would then be shoved
13 out and you would have seen partials. In fact, you're seeing
14 that the very bottom of one of the tablets, is slightly
15 covered. You just can't quite squeeze it all in. But it was
16 meant to be representative to show what the tablets looked on
17 both sides.

18 Q. Let's look at 24.02.

19 Is this one of the photos that you took?

20 A. Yes, sir, it is.

21 Q. What is this depicting?

22 A. This is depicting the type of tablets that you see
23 in the second line over here with the M in the large square
24 with rounded edges, and the backside has the 30 on it, the
25 debossed 30 with a half score.

1 Q. And let's look at 24.03.

2 A. Now these are oblong tablets, and these are from
3 the bottom one over here from Items 14 through 19
4 representative of those with the GG249 with the three-quarter
5 scores. As you see, there are only two tablets in this one.
6 For the same reason, these are larger tablets and we could
7 only get those into the image as you see here.

8 Q. And let's look at the next photo 24.04. What are
9 we looking at here?

10 A. Now this is a tablet punch tip. And if you will
11 notice on it the upper right you can see the inverted GG that
12 we're talking about over here, and then the next block coming
13 down you'll see a 2 inverted. The next one down you'll see a
14 4 inverted, and at the very bottom you'll see the 9 inverted.
15 This is the tablet punch tip with the embossed features. The
16 embossed features are the ones that are sticking up that will
17 make the debossed features into a tablet once it's pressed.
18 And this is representative of those.

19 Q. Let me look at Exhibit 24.05. And what are we
20 looking at here?

21 A. This is another one of the tablet punch tips
22 representative of the type over here that we had with the
23 20 -- Item 21. And you'll see we had nine of those. Those
24 have the M, capital M enclosed within the rounded-edge square.
25 And this type of appearance that you see here you're seeing

1 the actual M. Again, it's the punch tip itself.

2 Q. And it looks like there's some sort of white
3 substance that's on the punch tip. Were you able to identify
4 what that was?

5 A. We did not. But there's so much -- there's
6 contamination on things. We see loose particles of stuff, we
7 do not collect in this particular area. But the images that
8 were captured initially were of the punch tips as received.
9 This is how we got them into the laboratory. This is what
10 they looked like. They were clean before processing.

11 Q. So after you've identified and paragraphed the
12 items that were received for analysis then what did you do?

13 A. Well, the work that I was going to do? My next job
14 on this one was to process these and prepare these images or
15 these tablet punch tips for analysis by, it's called 3D image
16 analysis. And what we would do with the 3D image analysis
17 will be explained by someone else. But it was my job to
18 prepare these.

19 What we would do is we actually -- I would clean
20 the surface of these, and some of the material will wash off
21 with a little bit of water and little bit of squirt bottle.
22 This is all done in a hood where the liquid is collected and
23 sent to hazardous waste afterwards. But I would clean the tip
24 of it off because we didn't get all of the particles out of
25 the or the deboss -- or the embossing that you see on the

1 punch tip, we would take a small cotton swab. It's on a
2 wooden dowel that we use in the laboratory all the time, a
3 clean one of those that's wetted with a little more water.
4 And then we would wipe the surface, get it cleaned off. And
5 if we still couldn't get the stuff out as much as we could,
6 you can actually take these wooden dowels, and you can snap
7 them, and it forms a very nice little probe. It's a soft
8 wood, and you can actually flair it a little bit so it becomes
9 kind of like a whisk. And you can take that with water
10 squirted on there and use that to get as much as possible of
11 the residue on the surface of these tablets removed. Then it
12 was wiped off with a chemlight, a little lab light that we
13 use, dried and then passed on for additional processing.

14 For additional processing, we want to be able to
15 compare the information, the embossed information on these
16 punch tips to the tablets. Well, you could if you wanted to
17 try to take a punch tip and look at it directly inverted under
18 a microscope, capture an image and then process and try to
19 compare images of that to the tablets. But you have to be
20 able to turn it over completely. You have to do a mirror
21 image of it flipping your head.

22 So what we did we developed a method a while back
23 in which we wanted to be able to take a look at what the
24 tablet would look like if it was produced by that punch tip.
25 So in order to do that, we developed a method using Mikrosil.

1 And Mikrosil, it's M-I-K-R-O-S-I-L. Mikrosil is a product
2 that is commonly used in the forensic community for
3 transferring toolmarks, anything from screwdriver marks on a
4 door lock hasp or something in which an investigating agent or
5 detective wants to collect information from that crime scene
6 they will take the Mikrosil. It comes in two parts, there's
7 the Mikrosil itself, and there's a hardener. And you put down
8 equal lengths of the material. You mix it up just like you
9 would an epoxy that you're going to do to make a repair on
10 something at home, you mix it up, and you have a little bit of
11 time. It doesn't set up real, real fast. But you smear it on
12 the surface of whatever. You allow it to sit on that surface
13 for a while. And then when you remove it it comes off as a
14 silicone mold. It all comes off beautifully and completely,
15 and it has a good permanence to keep it around for a while.

16 What we did is we developed a method to develop
17 Mikrosil to make essentially -- we're taking tablet faces the
18 way the tablet punch tip would make that particular tablet if
19 it were there. But instead of using tablet material we're
20 using the Mikrosil.

21 And I would take a punch tip and invert it so it
22 was pointed up in the air and the punch tip was up above me.
23 We would mix up the Mikrosil, and we dab. We just don't smear
24 it on like we're smearing butter because you won't go down
25 into those little pockets, in little places and indentions.

1 You'd have to do a lot of sticking and stuff like that to make
2 sure you're getting everything well coated. Then a little
3 bit, leave a little bit of a bleb of the Mikrosil above it.
4 And then the remainder of the material of the Mikrosil that
5 you mixed up is in a plastic petri dish just like we've
6 described before, take that and invert that and put that down
7 smoothly and flatly on the top of that surface, and then leave
8 it alone for 20 minutes to an hour.

9 When you come back and remove it, it pops out just
10 beautifully. You'll have a perfect rendition of that surface
11 down to micro details. Mikrosil does a beautiful job of
12 transferring even very, very small striations or marks or
13 blemishes or irregularities in the surface of any feature that
14 it's used on.

15 It comes in a number of colors. There's a brick
16 red, a black, a white and a grey. We determined a while back
17 that the grey was the best because it let's us see the
18 features well, but we don't get high reflectance in the
19 microscope back into the -- to distort images or cause
20 problems during analysis.

21 And then these were capped over with the top the
22 petri dish that's label with whatever punch tip was used to
23 make that. It will have the sample number on it. It will
24 have the item number on it. It will have the date in which it
25 was prepared. It will have my initials on it. And then since

1 we did multiples we would do them as Roman Numeral I, Roman
2 Numeral II and Roman Numeral III.

3 Q. For which punch tips did you actually create these
4 Mikrosil capsules?

5 A. I did if for all of the ones we have identified
6 over here. All of the GG249s, and all of the M encased in the
7 rounded-edge circle.

8 Q. And how many casts for each punch tip did you do?

9 A. Three.

10 Q. Why do you do three?

11 A. We do three for several reasons. Number one, you
12 can't always tell right away when it goes to the 3-D images
13 equipment, it's profilometer, which will be discussed later.
14 But you can't tell just by glancing at it real quickly if
15 there are small bubbles or something in the surface of it.
16 We've gotten to where we're really quite good at it. But if
17 you see some, it's rejected and we make another one. That's
18 the beauty of it. You can make all that you want to because
19 you're not hurting anything.

20 But in this case we try to get three that look the
21 best. So you would be able to have repetitive -- you know, if
22 there is an irregularity uniqueness to this punch tip that we
23 would be making multiple copies of that that could also be
24 determined, yes, this is consistent between these punch tips.

25 Q. So at the lab where you work more often than not

1 you're working in teams; that is right?

2 A. Yes, sir.

3 Q. And as a lead analyst you're responsible for kind
4 of coordinating amongst the other analysts?

5 A. I don't coordinate it. I'll be the pressure.
6 Where is your analytical section, because it's -- I'm the one
7 who has to prepare the final report. But everyone is given
8 their sample whether they were given tablets or whether they
9 were given punch tips or anything. I do not follow them in
10 their work or their analyses. They go on. They process
11 theirs the same way I did mine for their techniques. And once
12 they have completed it they would have to have their work
13 checked and reviewed. And then they get back what's called an
14 analytical report for their discipline, for their section.
15 And that goes into our record. It's all logged in.

16 What I will do as the lead analyst is in the end I
17 will, of course, include all the information that I put in
18 here plus the identification information of the items that
19 were within the sample as received. But I will also include
20 the lines from their verbiage from their analytical reports as
21 to what their findings were, synopsisized into a small sentence
22 or a couple sentences or paragraphs. That all goes into the
23 final report.

24 That report is then reviewed by my superior and by
25 another person who will go through and make sure that

1 everything is correct. They will review all of the analytical
2 sections that were part of this particular work. They'll
3 review what has been done there. And they will also make sure
4 that, again, the correct forms were used, that it's clear,
5 that it's understandable. And before anything even leaves
6 every analyst who submitted a portion of their work, their
7 section that was contributed to that analytical work has to
8 sign off on the final report, as well. And there's a place on
9 there for their name, and their analyst number goes on there
10 so that you know that they were part of it and you could
11 follow which work they had done. We can backtrack it that
12 way.

13 Q. How many analysts were involved in performing tests
14 or examining these items?

15 A. If I may look at this to count, I have to take a
16 look.

17 Counting myself there would be five people.

18 Q. And prior to your testimony today did you list who
19 those individuals were that performed some form of analysis or
20 some step in the analysis to tell us what they did?

21 A. I did. I did. I prepared this in advance.

22 If I may stand up and flip the chart.

23 MR. BURGGRAAF: And with that, no further
24 questions, Your Honor.

25 THE COURT: Thank you.

1 You may cross-examine.

2 MS. BECKETT: I have no questions for this witness,
3 Your Honor.

4 THE COURT: Thank you, Ms. Beckett.

5 You may step down.

6 THE WITNESS: Thank you.

7 THE COURT: You may be excused.

8 And the government will call its next witness.

9 MR. BURGGRAAF: Your Honor, the government will
10 call Nicola Ranieri.

11 THE COURT: Come forward and be sworn, please, at
12 the podium.

13 THE CLERK: Just right here. Just raise your right
14 hand.

15 NICOLA RANIERI,
16 called as a witness at the request of Plaintiff,
17 having been first duly sworn, was examined
18 and testified as follows:

19 THE WITNESS: Yes, I do.

20 THE CLERK: If you'll just come around to the
21 witness box here.

22 Please state your name and spell it for the record.

23 THE WITNESS: Nicola Ranieri. N-I-C-O-L-A,
24 Ranieri, R-A-N-I-E-R-I.

25 THE COURT: You may proceed, Mr. Burggraaf.

1 DIRECT EXAMINATION

2 BY MR. BURGGRAAF:

3 Q. Mr. Ranieri, can you tell me what your current
4 occupation is and who you work for?

5 A. Yes. My current occupation is a forensic scientist
6 at the Food and Drug Administration Forensic Chemistry Center,
7 which is a specialized laboratory that was forensic for the
8 FDA.

9 Q. And throughout your testimony I may refer to that
10 as the FDA lab. How long have you been working at the FDA?

11 A. Quite a long time. I was essentially co-oped while
12 I was going through my undergraduate at UC since August of
13 1989, so it was 30 years.

14 Q. And at the FDA lab what are your job
15 responsibilities?

16 A. Well, I'm a scientific, microscopist. I do various
17 forensic related analyses. You know, tampering,
18 counterfeiting and various other consumer complaint samples
19 cases.

20 Q. And what's your education background?

21 A. I have an undergraduate degree from the University
22 of Cincinnati, Bachelor of Science degree.

23 Q. And did it have a focus as far as your Bachelor of
24 Science?

25 A. That's correct, yes. Biology.

1 Q. And do you have any additional training that
2 relates to your current responsibilities?

3 A. Actually, yeah. I have quite a few, but over the
4 years, you can imagine. So I've taken many courses. For
5 specifically for this case I'm going to pick the ones that
6 relate to this moment here. So I took a Confocal microscopy
7 and image analysis at George Washington Medical School. I
8 took a computer-assisted image analysis at North State
9 University in North Carolina, State University, a
10 computer-assisted image analysis at Rochester Institute of
11 Technology.

12 I have had multiple others in the toolmark arena,
13 such as Dayton Crime Laboratory toolmark analysis training. I
14 had regional crime laboratory from Dayton in toolmark
15 analysis. I had an ATF toolmark analysis training at the
16 coroner's office in Cincinnati, Ohio. And I also have taken a
17 tablet formulation and design in manufacturing tablets and
18 tablet punches at the training facility in St. Louis,
19 Missouri. I could go on.

20 Q. But you don't need to. You sound like you've had
21 quite a bit of training.

22 A. Yes.

23 Q. Do you provide training or have you provided
24 training to others in your field of expertise?

25 A. Yes. You know, there's many inference related, so

1 I'll pick a few again. One is the, it's a German name. I
2 can't pronounce that one. So it's a Food and Drug
3 Administration like agency. But it's a chemistry and physics
4 in Vienna, Austria, analyst that came to our laboratory, and I
5 trained him. There's the forensic science -- forensic
6 chemistry scientists at the city of police in Taipei, Taiwan.
7 Forensic science and physics laboratory from Singapore. These
8 are agencies that do similar things that we do, and many other
9 within the Food and Drug Administration and other agency like
10 Food and Drug Administration nationally.

11 Q. Have you published articles or literature in areas
12 of your expertise?

13 A. Yes. I published many. But for this particular
14 one it would be, the most appropriate is the 2-D, 3-D
15 examination of tablet formulations and for suspect
16 counterfeiting and tablet sourcing. So that one's done at the
17 microscopy microanalysis in 2010.

18 Q. And you actually hold a patent for some of what you
19 do?

20 A. Yeah. I was lucky in my career because the
21 laboratory started when I started back in 1989. So everything
22 was new. So eventually I came up with a -- when you look at
23 tablets and someone hands you a bag of tablets you have
24 thousands of tablets. To look at them all it's not easy
25 through a microscope. So eventually I came up with something

1 called alternate light source technology where essentially you
2 spread out all of these tablets. You illuminate with a
3 specific light in a wavelength whether it's UV visible and
4 infrared, and then you can see the difference between a
5 suspect generally.

6 Then I created -- with that knowledge I created a
7 device that now today I have two full patents, one pending
8 international and three European patents pending still on the
9 device, and the FDA uses these device to detect or red flag a
10 suspect.

11 Q. And have you testified as an expert before?

12 A. Yes.

13 Q. How many times?

14 A. Three. But specifically the one in this case last
15 year was about three.

16 Q. And has the court ever made a finding that your
17 testing methods or results were not accurate or correct?

18 A. I'm sorry. Could you repeat that?

19 Q. Has the Court ever made a finding that your testing
20 methods or results were inaccurate?

21 A. No. No.

22 Q. Have you had training and experience in analyzing
23 pill press punches and dies?

24 A. Yeah. As I stated earlier I took an actual course
25 from a company called Natoli. They actually manufacture

1 presses and tool punches. And they actually have a facility
2 that train you and whoever wants to be a tool press operator.
3 So I took that course where that is, you know, the design that
4 punches a design, the tablet formulation, and they show how
5 to, train you how to run a press.

6 Q. And what did you do to prepare for your testimony
7 today?

8 A. I reviewed the work I did when I actually did the
9 work.

10 Q. How did you become involved in this case?

11 A. I received -- at our laboratory you have a lead
12 analyst, and then you have everyone else that follows. A lead
13 analyst is usually the analyst that receives the case. And in
14 this situation Mr. Platek was the lead analyst in this
15 particular case, so he did what we call a Section One.
16 Section One is an overall over everything that he's received.
17 Part of the supervisors and management of the laboratory is
18 instructed to have this technique done. So I was one of those
19 techniques that was supposed to analyze these tablets.

20 Q. So in your role in this case were you directed to
21 analyze and compare the tablet punches embossed with GG249
22 comparing them to each other and to tablets that were debossed
23 with GG249 in Items 14 through 19?

24 A. Could I ask you to repeat that? Sorry.

25 Q. Were you directed in this manner to analyze the

1 tablet the punches --

2 A. Yes.

3 Q. -- embossed with GG249?

4 A. Correct. Yes, I was.

5 Q. And compare them to each other?

6 A. Correct.

7 Q. And then compare them to the tablets or pills that
8 were in Items 14 through 19?

9 A. Correct.

10 Q. Were you also directed to analyze the tablet punch
11 tips embossed with an M and enclosed with a square comparing
12 them with the tablets that were debossed in a like manner?

13 A. Correct.

14 Q. What process and equipment did you use to perform
15 your analysis?

16 A. The technique is called profilometry. In our
17 laboratory we have an array of disciplines and
18 instrumentations. When we have visitors usually these
19 visitors go through all these techniques. And the microscopy
20 because it's visual as well as analytical is the most
21 attractive. I wish I had a way to show you what a 3D image
22 looks like, 3 dimensional image looks like. A system that is
23 called IFM, Infinite Focus Microscope. What it does
24 essentially is it scans. It measures the surface of a sample.
25 When it's finished collecting the whole surface it displays it

1 as an image, but it's really not an image because it has just
2 data points.

3 Q. And did you use any other instrumentation or
4 equipment in performing your analysis of the punch tips and
5 the tablets such as 3DIA?

6 A. Yes. That instrument is called, we refer it to as
7 3DIA, which stands for 3-dimensional image analysis. It's
8 considered a profilometer, so it was a technique called
9 profilometry. The system, actually what it does is it
10 collects -- if you envision a picture, just a picture, that's
11 a flat image, so it's 2D. It's considered a 2D image. So you
12 have an X and a Y that dictates where the point for that
13 pixel. So, for example, X direction and a Y direction, then
14 you find the two values and that's a point. That's a pixel.

15 In this case, the system creates X, Y and Z, which
16 is the height. So you have two dimensional, and three
17 dimensional makes the height.

18 Q. So talk to me about this 3DIA instrument. What is
19 it composed of? What does it look like? And how does it
20 operate?

21 A. It's a big microscope. It is a big microscope that
22 has a precision movement stage. It moves in micrometer.
23 Actually nanometer steps, and it has a sensor that illuminates
24 the sample and collects, if you will, an image, but it's
25 really data of the value of that XYZ point. The XYZ point in

1 particular for this case when it scans the whole surface, if
2 you can envision X5Y10 and Z15, that's one data point. This
3 collects 6.3 million pixels. To makes it easy, it's
4 6.3 million data points. So picture 6.3 million of those, and
5 it takes those points and compares to a known would equal
6 number of points, and it as an algorithm, and it calculates
7 and XYZ location right here at this three-dimensional space.
8 Does this unknown have this point right here? Yes or no? If
9 it does, it's counts it as a yes, it has it. After
10 6.3 million points it gives you a percentage of how many of
11 those points found the same at this from a known authentic to
12 an unknown suspect.

13 Q. Let me see if I understand, if I can explain that
14 correctly. Using this 3DIA equipment you can put a pill in
15 front of the equipment and it's going to gather from the
16 surface of that pill essentially 6.3 million data points?

17 A. That's correct.

18 Q. You can put another pill and get 6.3 data points
19 that you can then compare those data points?

20 A. That is correct. Yes. So the beauty about this
21 technology, this technique, this instrument is that it's
22 extremely consistent. And prior to any analysis, this
23 analysis or any analysis I've ever done with any technique
24 really in this case with this 3DIA system we also measure also
25 an authentic where we already know the data and results so we

1 can confirm that, yep, we got the same results as we got in
2 2010, 2015, last month.

3 So the tablet that it collects these points is then
4 saved the data. It's called data set. Then we have a library
5 of authentic. We call that up, data set, and we tell the
6 system, okay, go ahead and compare these two data sets, and
7 return a percentage.

8 Or there's another technique that's called profile
9 measurements that actually gives you a cross section of that
10 particular surface, and it compares if these two profiles line
11 up exactly or not. If it doesn't, you'll be able to visually
12 see it.

13 Q. So you can compare one pill to another. And when
14 you reference authentic is you referring to official
15 manufactured tablets from the official manufacturer?

16 A. That is correct. We -- because we do always a
17 comparison with an authentic we always have to have authentic
18 from a manufacturer. So if we don't have it, then we
19 communicate -- well, myself, for example, I requested, through
20 the proper channels I request an authentic so I can use it in
21 my analyses. And then there's a special group that actually
22 reaches out to the genuine makers, genuine makers of a
23 particular product, and it requests as an FDA agency to send
24 us some authentic. So it usually sends us a bottle of
25 tablets or capsules.

1 So in this case we had all three already, and we
2 had those in the library already. So that is the process, so
3 comparing to what we call authentic. Also we consider that a
4 known because we have a known value.

5 Q. Now, we talk about comparing pills to pills.

6 A. That's correct.

7 Q. Can you also use this 3DIA analysis to compare
8 pills to punch press tips?

9 A. Yes. That's correct; because the system pretty
10 much can scan or measure anything you put underneath this. So
11 in this case we can put the tablet punch under there, or we
12 can create what is called casting using Mikrosil. And then we
13 have the actual. Such a Mikrosil is a way to create the same
14 surface as the punch tip that made a tablet. You take that
15 same punch tip. You put Mikrosil on the top. It's kind of
16 like making an identical tablet that this punch tip will make.
17 So then we compare the punch tip or the Mikrosil to a tablet.

18 Q. In this case, before you began your analysis in
19 using via equipment did you verify that the equipment was
20 operating adequately?

21 A. Per our SOPs and per, you know, the laboratory you
22 cannot proceed without what is called a verification to make
23 sure that the system is running as it was yesterday.

24 Q. So you talk about these data sets and the potential
25 for at least in one aspect of it to collect 6.3 million data

1 points.

2 A. Correct.

3 Q. Am I correct in assuming that you're using the --
4 essentially the microscope is taking an image, but that's
5 taking those data, that net data, and you're then using a
6 computer to process that data?

7 A. Yes. It's a system. So the microscope is coupled,
8 it's attached to a computer. The computer runs the microscope
9 essentially. So the computer will collect the data that the
10 sensor is picking up and transfers electronically obviously to
11 a computer. The computer then converts that signal to a data
12 point or data points, and it saves it. I'm prompted to save
13 it or not, then I save the image. I hate to use the word
14 image because it really isn't an image because you see it.
15 It's really a wire frame of value points. It's not really an
16 image, but to make it easy for humans they give you an image.

17 So it takes these points, then I call up the same
18 software, call up the data set of the one that I just scanned,
19 just measured, call up the data set file of the known or
20 authentic or genuine. And the system has multiple ways of
21 comparing. I pick what is called difference measurement
22 analyses as well as profile management analyses.

23 Q. We'll maybe get to having you distinguish what each
24 of those mean. Before we do did you document your findings
25 after performing this analysis?

1 A. Yes. At the end of the process that the system is
2 comparing it to it prompts to save a PDF file for the report,
3 which is a report. Then we take those reports and pile them
4 up, save them. And then you take -- after you finished
5 collecting all of your items, tablets or punches or Mikrosil,
6 and when the whole work is complete then you put this package
7 together, which we call a section.

8 Q. Let's look at some of essentially your findings.
9 If we can look at Government's Exhibit 24.09.

10 Am I accurate in stating this is a comparison photo
11 of a tablet punch tip, a Mikrosil cast of a tablet punch tip
12 from Item 22 to an actual tablet from Item 17? Is that
13 correct?

14 A. Yes, that's correct.

15 Q. So tell me what we're looking at in this exhibit.

16 A. As mentioned, the image on the left, which is
17 shiny, metallic looking, that is the tip what we call the
18 tablet punch tip. That is the phase that actually comes in
19 contact with the powder that eventually is pressed to make a
20 tablet, so that's a punch tip.

21 The one in the middle essentially is a Mikrosil, a
22 casting of that punch tip. Essentially is treated, the punch
23 tip is treated with Mikrosil as if you were making a tablet.
24 So instead of making a tablet you're making a casting which is
25 similar to making a tablet. And the far right, the brownish

1 appearance, that's the tablet, Item 17, Tablet 1.

2 So looking at these three here put together, the
3 reason this was put together is because through the process of
4 tablet making just like any technique you have to essentially
5 take care of your instrumentation. So the punch tip, it's a
6 tool that makes the tablets. Therefore, if you don't take
7 very good care of that damage occurs through changing, through
8 replacement, through to a high pressure, anything that causes,
9 in this case, there's a green arrow, that causes a dent. You
10 can see the little dent on the bottom of the edge of the
11 metallic looking punch tip. There's a green arrow pointing,
12 as you can see it's over exposed only because, you know, it's
13 shiny. But there is a tiny little bump as you see it coming
14 inward. That's on the edge of the tablet punch tip cup. The
15 cup is what essentially makes the shape.

16 On the center you have a Mikrosil with a green
17 arrow also points to the same. As I explained it earlier the
18 punch tip once it presses onto a powder to make a tablet it
19 essentially transfers everything, every shape of it. In this
20 case that little dent was transferred into the Mikrosil. If
21 you see on the far right you see the same dent on the tablet
22 that was pressed by that punch. Because of the location it's
23 quite evident that that punch tip appears to have made that
24 tablet.

25 And on the red arrows, I just wanted to bring that

1 point out. I can, can't I?

2 Q. Yes.

3 A. It's an important part because punch tips are made
4 typically by what's called the master hub. Master hub is the
5 master punch tip, and that's where all the other punch tips
6 will be made. So when a manufacturer manufactures the punch
7 tips and they make the master, consequently after that, they
8 make other punches using this master. The master is made with
9 high strength steel that is treated to be harder than a metal
10 that they make for when you make a punch tip. So you take
11 this master and it press it with extreme pressure and
12 transfers what's on the hub onto another punch tip, so you
13 created a punch tip.

14 The reason I'm explaining this is because the
15 master hub, the design, the original punch tip, that punch
16 tip, the punch tip makes all the other punches, it's called
17 the hub. It's made with -- in this case you can see the
18 lines, I don't know if you can see those lines. You know,
19 forgive me about the compression of PDF, but it was quite
20 clear on the actual image, those are called CNC process.
21 That's process called computer numeric calculations. And that
22 is what made the master hub.

23 So those lines are made through the process of
24 making a hub, which then later the hub which is the master
25 will press onto another softer metal to make the punch tips.

1 So that punch tip there with those lines and that arrow, you
2 can see the casting Mikrosil in the center that shows the same
3 centrifugal CNC lines, and you can also see them on the
4 tablet.

5 Q. So can you use essentially a comparison of the
6 defects or characteristics of a punch tip to determine whether
7 a pill or tablet was made by that punch tip?

8 A. The process of making a tablet punch is revealing
9 that the process that took place of making that punch tip.
10 When there is a damage or a dent or nick or burr on a punch
11 tip it's kind of like creating its unique fingerprint.

12 So if I were to press my hand on here, take it off
13 and it left a mark, that mark there is essentially my hand.
14 If I cut myself and I press on it you're going to see the cut
15 there. So when there's a damage on a punch tip it will
16 continue to replicate that on all the tablets that it makes.

17 Q. Okay. Let's go to Government's Exhibit 24.10.
18 What are we looking at here?

19 A. This technique -- again, this is profilometry. And
20 this particular technique is called profile measurement.
21 Please tell me if I need to move this closer. Profile
22 measurement. Yes. The grey image on the upper left corner
23 with the red band across it, that one there is a casting of
24 the punch tip. The red band is what the system will take and
25 calculate a cross section of that line. On the right side of

1 the grey image is the profile, the cross section of that red
2 band on that casting material. Beneath it below the grey
3 image you have a brown, which is a tablet with the same red
4 line going across it creating again its own profile.

5 You take the two profile diagrams on the right of
6 the tablets, and the system is then, compares the two
7 superimposed and overlays them together. And anything that
8 overlays quite well tells you that it's a pretty good,
9 pre-consistent to it to each other.

10 Q. The jury has heard prior testimony about these
11 Mikrosil casts being made of the punch tips that were
12 provided. They also heard testimony that the punch tips for
13 this specific drug exhibit number was found on the floor of a
14 bedroom in the defendant's home. That would be Item 20. It
15 appears that Item 14 as you stated was one of the Alprazolam
16 pills that was analyzed; is that right?

17 A. That's correct.

18 Q. And the jury heard prior testimony that Item 14 had
19 a specific DEA exhibit number which correlated it to prior
20 testimony of a pill that was seized from codefendants Tonge
21 and Bustin in November of 2016. With what we are seeing here
22 on the comparison of these two times what can we conclude as
23 far as the punch tip from the defendant's home and the pill
24 that came from a codefendants' home?

25 A. What I can conclude is that the two are consistent

1 to each other.

2 Q. Let's go to Page 2 of this exhibit.

3 Now I made a mistake of leaving out a page which
4 deals with if I remember difference measurement analysis.

5 A. That's correct.

6 Q. Why don't you explain what difference measurement
7 analysis is.

8 A. Just what I'm seeing here is a half page. Is that
9 what I'm supposed to see?

10 Yeah. Thank you. Okay. So this is the second
11 page of essentially describing what the system did prior to
12 this. The difference measurement module, which again, is a
13 different technique than the profile measurement module. The
14 difference between the two is, one, as I mentioned, one
15 creates a cross section of my hand so you can compare the two,
16 the line and gives me a line so you can compare that line; the
17 other one, the difference measurement, in this particular case
18 this is a difference measurement, it takes the tablet and it
19 essentially measures every parts of that tablet. Again,
20 repeating it again, but it is what it is, 6.3 million XYZ
21 locations points. That is it.

22 These points are then calculated, the algorithm
23 calculates between what we just saw, the grey casting and the
24 tablet and gives how many -- what is the percentage of the
25 same exact location that the system saw? 6.3 million points

1 of XYZ locations, 97 percent and slightly higher than that
2 were in the same location, which that translates to they're
3 consistent, very consistent to each other.

4 Q. Does that mean that it is pretty likely that the
5 punch tip analyzed created the pill analyzed?

6 A. Yes, correct.

7 Q. Let's look at Exhibit 24.11. Can you explain what
8 we're looking at here?

9 A. Yeah. This is -- okay. Obviously these are
10 punches, and this is a good example of what we talked about
11 just a bit ago about creating its own individual fingerprints.
12 In this particular case the images that are labeled A and the
13 center one B and the one to the right C, they're all showing
14 what in this discipline is called sticking, picking and
15 sticking. Sticking and picking. And it is exactly that. It
16 is material sticking to the punch face to the punch tip. And
17 that is a lot of times is due to poor maintenance of the tool.

18 For example, one of the things that one could do to
19 avoid material sticking as you can see on image B, underneath
20 it shows up close the 9, there is a type material that is
21 stuck to it. That type of material is essentially for as long
22 as it's on there it will create its own additional fingerprint
23 to whatever it stamps, whatever tablets it makes.

24 So this really happens when -- for example, you
25 wouldn't drive a car 100,000 without changing your oil. You

1 have to do some cleaning. You have to maintain it. So
2 maintaining your tools is your livelihood. So without doing
3 cleaning, often cleaning this can happen. There are other
4 reasons that it can happen, but this is typical of potentially
5 low maintenance. And when you do low maintenance on these
6 tools it stays, that material stays on there for as long as
7 it's able to adhere to it.

8 The one on the C shows a lot more material stuck to
9 it. And that is actually going to be transferred on tablets.
10 The A was rather clean. There was nothing sticking to it. So
11 that one there will create an exact image or a higher quality
12 image when you compare it to a casting with the Mikrosil
13 because it's nice and clean. The one further to the right,
14 the C or the B, those have additional variations to
15 fingerprints such as material stuck to it.

16 Q. So if there was a punch tip that has some sticking
17 and picking, it's going to carry over the defect to the pills
18 that it punches and are created.

19 A. That's correct. A lot of times that happens when
20 in the tableting production, manufacturing, you have
21 essentially what is called cohesiveness forces and adhesive
22 forces. So when the packing, the pressure to make a tablet,
23 the cohesiveness of the formulation, if it's not as strong as
24 the adhesiveness of the cup essentially being more attractive
25 to it material will come off and will stay to it. So a lot of

1 that happens when again maintaining the tools, adding
2 lubricant to the formulation, things like that.

3 Q. We are going to look at some more comparisons that
4 you made between Mikrosil cast of the punch tips and pills
5 seized in this case. The jury has previously heard that prior
6 to creating those Mikrosil casts that Mr. Platek actually
7 cleaned them off. When we're looking at that percentage in
8 comparison, if the picking and sticking is removed is that
9 going to cause a difference in that percentage?

10 A. Correct. Yes. Correct. And I believe I do have
11 some data to show where the picking may have been. So, yes,
12 correct.

13 Q. Let's go on to Exhibit 24.12. Why don't you tell
14 us what we're looking at here. It looks like a similar
15 comparison, but this time from Item 14. Again, an Alprazolam
16 pill that was seized from the Tonge/Bustin home to what the
17 jury has heard testimony about, an Alprazolam pill that was
18 seized from a net basket in the defendant's basement. Tell me
19 in comparing those what are we looking at here?

20 A. Okay. What you're seeing is the profile
21 measurement. In this profile measurement you have two tablets
22 that is actually a 3D image converted into a JPEG. But each
23 of these tablets with the red band I described earlier creates
24 a diagram. So tablet -- I'm sorry. Item 14, tablet 3, here's
25 the diagram on the right side. Item 18, tablet 1, the diagram

1 is on the right side. The beauty about this particular one is
2 the debossing was nice and clean. Therefore, they're
3 practically indistinguishable because there was no unique
4 individual fingerprint due to sticking and picking.

5 Q. Let's look at Page 2 of the same exhibit, if you
6 can zoom out.

7 Explain this aspect of your analysis on comparing
8 these two pills.

9 A. So. Yes, thank you for zooming in. So here this
10 is the difference measurement module. Again this will take
11 one tablet and measure every component of that, every part of
12 that surface to every other part of the other surface and look
13 for the XYZ 6.3 million points and comes back with a result
14 that says how many at this point in this percentage map the
15 same location? In this particular case as you can see it was
16 very little sticking in there, so the percentage is quite
17 high.

18 Q. Is it fair to say that based on your analysis that
19 each of these pills that came from different locations were
20 actually made from the same punch tip?

21 A. Yes. Based on the analysis that we do authentications
22 to authentications, when you see numbers like this they do come
23 from the same place.

24 Q. Let's look at Exhibit 14. And you've given quite a
25 bit of explanation as to how to more or less compare or how

1 these are compared. This appears to be a tablet from Item 14,
2 which the jury heard testimony came from the Tonge/Bustin
3 home, to Item 19, which was seized by postal inspectors
4 according to prior testimony. Are these essentially
5 Alprazolam pills that were likely to have been made by the
6 same punch tip?

7 A. Based on the comparison with the casting, yes,
8 they're very consistent.

9 Q. Let's look at Page 2 of this exhibit, as well, if
10 you'll zoom out.

11 Again, like the prior exhibit, it looks like
12 there's a high percentage of those 6.3 million data set,
13 there's a high percentage of them being exactly aligned with
14 each other; is that right?

15 A. Correct.

16 Q. Let's go to Exhibit 24-14. Again, looking at a
17 similar diagram but comparing a punch tip which the jury heard
18 testimony was found on the floor of the defendant's home to
19 what appears to be an authentic Alprazolam pill; is that
20 right?

21 A. Correct.

22 Q. And how did the punch tip compare to an authentic?

23 A. As you can see the two diagrams related at the
24 bottom, they have very little resemblance to each other, not
25 consistent with each other.

1 Q. And let's look at Page 2. And what would we
2 conclude from the information here?

3 A. That the lower percentage such as that one there
4 are quite a few XYZ locations that are not the same location
5 as the comparing sample.

6 Q. Let's look at the next exhibit, 24.15. This
7 appears to be a comparison of a Mikrosil cast of one of the
8 punch tips for an M box or Oxycodone punch tip. The jury
9 heard testimony that items for this exhibit actually came from
10 a pill press from Mr. Shamo's home on Titian Way that actually
11 is compared to a tablet in Item 8, which is a tablet that came
12 from the Tonge/Bustin home. What can we conclude from what
13 we're looking at here?

14 A. Once again, the two diagrams are overlaid at the
15 bottom. While they may not be over top of each other as the
16 previous there's a lot of sticking and picking going on in
17 that particular tablet. They're very consistently consistent
18 to each other.

19 Q. The sticking and picking that may have gone on in
20 the creation of that tablet, can the mere fact that the punch
21 tip being cleaned prior to creating the Mikrosil casts account
22 for some of the difference?

23 A. I'm sorry. Could you repeat that?

24 Q. So as the jury heard in prior testimony that the
25 punch tips were, any debris was cleared off of them --

1 A. Correct.

2 Q. -- creating the Mikrosil cast. Can the fact that
3 some of that debris being cleared off prior to creating the
4 cast account for some of the difference between the Mikrosil
5 and the actual tablet?

6 A. Correct. That is typical when you remove material
7 from such sticking and picking. But the overall shape as you
8 can see is quite consistent.

9 Q. Let's look at Page 2 of this exhibit. What can we
10 conclude from in information?

11 A. Once again, is not as high as the 99 percent, but
12 it is quite close. The XYZ locations were quite consistent to
13 each other in the 6.3 million points there. So this was very
14 consistent to each other.

15 Q. The defendant has been charged in part for pills,
16 the possession of pills at locations other than his own home.
17 If the punch tip came from his own home and these pills came
18 from another home, what's the likelihood that the pills were
19 originally made by that punch tip in the defendant's home?

20 A. Quite high.

21 Q. Okay. Let's go to 24.16. Here it looks like it's
22 noted that we're making or you're making a comparison of a
23 Mikrosil cast of a punch tip of an M box or Oxycodone punch
24 tip. The jury heard testimony related to the DEA drug exhibit
25 number that this came from Mr. Shamo's home on Titian Way, the

1 punch tip did. And it looks like it's being made -- or
2 compared to a specific suspect pill that is in Item 12 that
3 was also seized from Mr. Shamo's home. What can we conclude
4 from your analysis depicted here?

5 A. That they are consistent with each other.

6 Q. And let's look at Page 2. Can a similar conclusion
7 be made based on the information we're seeing here?

8 A. Yes, correct.

9 Q. Let's look at Exhibit 24.17. And I promise not to
10 belabor this any longer past this. What are we looking at
11 here?

12 A. This is actually really is my favorite type of
13 analysis because here the colorful little area there is to
14 describe what really, you know, sticking and picking is doing
15 to the fingerprint of this. The arrow, you know, that's
16 pointing to the diagram will show why that -- yes, beautiful,
17 thank you. The tips are gone. You know, if you see, for
18 example, the bump, on the left side there's a bump and going
19 down and back another bump, the one on the right, there's
20 quite of material missing. If we zoom out, a similar
21 situation is at the bottom showing what's missing there. So
22 you have the little bump in the diagram. So this was a way to
23 describe why you see some areas that don't, they do not have
24 right on top of each other. So that is due to sticking and
25 picking.

1 Q. So it looks like you have a red arrow on the second
2 diagram towards the top. Is that what's depicting then, that
3 as well as the other depicting where there's --

4 A. There's picking all over there, yeah.

5 Q. And the jury previously heard testimony that linked
6 the DEA exhibit from Item 21 to a pill press in Mr. Shamo's
7 home that's stated previously with the suspect pill Item 13
8 coming from a DEA exhibit that was seized by postal
9 inspectors.

10 While we have some what you explained as picking
11 and sticking with the suspect pill, what conclusion can we
12 reach even with that picking and sticking?

13 A. That this is consistent with each other.

14 Q. I want to pull up side by side if we can.

15 THE COURT: I assume you've got -- Mr. Burggraaf, I
16 assume you've still got some time about this witness.

17 MR. BURGGRAAF: In fact, I'm on my last probably
18 three or four questions.

19 THE COURT: Oh, all right.

20 MR. BURGGRAAF: If I may. If we can pull up
21 alongside what we're looking at here, the photo 24.05.

22 Q. BY MR. BURGGRAAF: You mentioned previously picking
23 and sticking. Is photo 24.05 an example of picking and
24 sticking?

25 A. An excellent example of picking and sticking.

1 Q. The difference that's shown between the Mikrosil
2 cast in 24.17 as compared to the pill, is that possibly due
3 because the picking and sticking was cleaned off of this punch
4 tip before making the Mikrosil cast?

5 A. Correct.

6 Q. And based on your -- actually if we can go back to
7 24.17 by itself, and look at Page 2.

8 And based on the information here as well as the
9 analysis you did on the prior page is it fair to conclude that
10 the punch tip that was found in Mr. Shamo's home was very
11 likely to have created the pill that was seized by the postal
12 inspectors?

13 A. Correct.

14 MR. BURGGRAAF: No further questions.

15 THE COURT: How much time do you think you need for
16 cross?

17 MR. SAM: I don't have any questions, Your Honor.

18 THE COURT: Thank you. You may step down and be
19 excused.

20 We'll take our first break.

21 (Whereupon, the jury left the court proceedings.)

22 THE COURT: Let me talk to your lawyers for a
23 minute. Others of you can go or come or sit or do whatever
24 you want.

25 I read your government's paper this morning. You

1 did not, the defense did not designate a medical expert to
2 opine on defendant's, any diagnosis of any particular malady;
3 is that correct? It is my understanding; correct?

4 MR. SKORDAS: Yes.

5 THE COURT: And I take it you're not intending to
6 designate one?

7 MR. SKORDAS: That's also correct.

8 THE COURT: Nonmedical expert -- nonmedical people
9 can't testify as to a diagnosis.

10 MR. SKORDAS: Right.

11 THE COURT: I mean, they can testify as to -- they
12 can't say somebody has X, Y or Z. They can give their
13 observations about things that are common that we all make
14 observations about, intelligence, ability to organize, certain
15 behaviors and all that.

16 But so I don't think there's really an issue there,
17 is there, having clarified that? You're not intending to try
18 to get an expert designation now?

19 MR. SKORDAS: Nope. And we don't intend to use
20 those witnesses as experts for the purposes of any medical
21 diagnosis.

22 THE COURT: Mr. Gadd?

23 MR. GADD: I just want to make sure we're all
24 clear. So in the opening it seemed pretty clear to me as I
25 reread it that was the intention for those witnesses. It's no

1 longer the intention? Or maybe it never was.

2 MR. SKORDAS: They can talk about his -- I mean,
3 it's his mother, Your Honor. She can talk about his growing
4 up, his perhaps learning disabilities, other things that
5 happened, not as an expert, but she would know as well as
6 anyone else about those things. And we can address those
7 through factual questions and avoid anything that appears to
8 be an opinion.

9 THE COURT: She can do that.

10 MR. GADD: Learning disabilities is a diagnosis.
11 ADHD is a diagnosis.

12 THE COURT: ADHD is clearly a diagnosis. I guess
13 she can testify about things that she observed that perhaps
14 she thought were learning disabilities without learning a
15 diagnosis.

16 MR. SKORDAS: That's all we intend to do.

17 THE COURT: That's fairly common.

18 MR. GADD: Sure. I think he indicates that it
19 might be factual, not opinion. I think it is opinion, though;
20 right? Isn't she going to give her opinion that perhaps, and
21 I don't want to put words in her mouth, but perhaps in her
22 opinion her son didn't or wasn't smart, you know, things of
23 that nature? I think it is opinions.

24 THE COURT: Well, every mother has opinions about
25 whether their kids are smart or not.

1 MR. GADD: Sure.

2 MR. SKORDAS: They're appropriate lay opinion, Your
3 Honor.

4 THE COURT: Some things are appropriate opinions
5 given by lay people, particularly lay people who know people
6 well.

7 MR. GADD: Yes, sir. I think those type of
8 opinions come in under 701. But what I worry about is
9 testimony such as, we took him to the doctor, and he got a
10 diagnosis and here it is. Or --

11 THE COURT: No. I'm not going to permit that.

12 MR. SKORDAS: Nor do we have any intention of doing
13 that.

14 MR. GADD: Okay. Thank you, Your Honor.

15 THE COURT: Thank you. We'll be in recess for
16 about 20 minutes.

17 (Recess.)

18 THE COURT: Do you have your next witness?

19 MR. STEJSKAL: Yes.

20 THE COURT: Let's get the jury.

21 (Whereupon, the jury returned to the court
22 proceedings.)

23 THE COURT: United States may call its next
24 witness.

25 MR. BURGGRAAF: United States calls Dr. Adam

1 Lanzarotta.

2 THE COURT: Come forward and be sworn, please, at
3 the microphone.

4 THE CLERK: Just right here. Please raise your
5 right hand.

6 ADAM LANZAROTTA,
7 called as a witness at the request of Plaintiff,
8 having been first duly sworn, was examined
9 and testified as follows:

10 THE WITNESS: I do.

11 THE CLERK: Please come around to the witness box.
12 Please state your name and spell it for the record.

13 THE WITNESS: Adam Lanzarotta. A-D-A-M,
14 L-A-N-Z-A-R-O-T-T-A.

15 THE COURT: You may proceed, Mr. Burggraaf.

16 DIRECT EXAMINATION

17 BY MR. BURGGRAAF:

18 Q. Dr. Lanzarotta, thanks for being here today. Can
19 you tell us what your current occupation is and employer?

20 A. I am a chemist for the Food and Drug
21 Administration's forensic chemistry center.

22 Q. And for simplicity throughout your testimony I'm
23 going to refer to it as the FDA lab.

24 A. Sure.

25 Q. Can you tell me how long you've been with the FDA?

1 A. 11 years.

2 Q. And what are your responsibilities in your
3 position?

4 A. I am a chemist, so we examine compromised FDA
5 regulated products for tampering, adulterations,
6 counterfeiting, diversion, things of that nature.

7 Q. You mentioned adulteration. What do you mean by
8 that?

9 A. Products that may have ingredients in them that
10 shouldn't have.

11 Q. And what's your education background?

12 A. I have a Bachelor of Science in Forensic Science
13 and Ph.D. in chemistry.

14 Q. And what training -- other than your education what
15 other training do you have related to your position at the
16 FDA?

17 A. I've taken a few courses specific to my particular
18 field of expertise at external -- with external outside FDA
19 and also internal FDA courses. And I've also instructed many
20 courses, as well.

21 Q. What type of courses have you instructed?

22 A. Specific to my field. So once we get into a little
23 bit later when we get into exactly what my field of expertise
24 is specifically, infrared spectroscopy. I've done a lot of
25 courses in that area.

1 Q. The infrared spectroscopy, is there an abbreviation
2 for that?

3 A. Sure. FTIR, and that is fourier-transform
4 infrared.

5 Q. FTIR. I'm going to use that, as well, because I
6 most definitely would mispronounce it.

7 A. Sure.

8 Q. Do you have any publications in your expertise?

9 A. Sure. I have several.

10 Q. Do you want to provide an example of one or two of
11 those?

12 A. Yeah. I've looked at a couple cases, counterfeit
13 tablet cases, so I've done some investigating in that. Also
14 in adulterated products, products like capsules and tablets
15 that have ingredients that shouldn't be in there, and using
16 novel techniques to examine those types of products.

17 Q. And then you published based on what you found?

18 A. That's correct.

19 Q. And have you testified as an expert before?

20 A. Yes.

21 Q. How many times?

22 A. I believe five or six.

23 Q. And has the court ever made a finding that your
24 test methods or results were not accurate or correct?

25 A. No.

1 Q. Have you had training or experience in identifying
2 and analyzing Oxycodone pills, Alprazolam pills and Fentanyl?

3 A. Yes.

4 Q. For today what did you do to prepare for your
5 testimony?

6 A. I looked back at over my notes, what we would call
7 bench notes or worksheets that we generated specific to this
8 case.

9 Q. We heard prior testimony from your colleague
10 Mr. Platek who explained that you performed two different
11 forms of analysis on items received by the lab, specifically
12 alternative light source and FTIR, the infrared. As far as
13 the alternative light source did you make any significant
14 findings related to your analysis there?

15 A. No.

16 Q. Moving on to the FTIR, can you explain what type of
17 analysis that is and the equipment that you use?

18 A. Sure. So it's a piece of equipment about this big,
19 2 feet, maybe, by about 2 feet deep, maybe, 8 inches tall, and
20 it has a small aperture on it where we take a portion of our
21 sample and put it on the aperture. And then we lower a
22 pressure arm on top of that to make a compressed pellet.

23 And the way the instrument works is we pass
24 infrared light through that window which is made out of
25 diamond. The light passes through that small amount of sample

1 and then gets directed back towards the detector. And based
2 on which wavelengths of infrared light that the sample absorb
3 we're able to determine a chemical fingerprint for that
4 particular substance.

5 Q. If I understand you correctly, then, the FTIR
6 process does analysis of pills received, and you didn't
7 necessarily do anything related to the punch tips that were
8 received.

9 A. Correct.

10 Q. Your colleague, Mr. Platek, previously wrote down a
11 list of categories of the items received by the lab. Does
12 that look accurate as far as the first three rows for what
13 analysis -- what items you did analysis on?

14 A. That's correct.

15 Q. I want to just confirm the type of tablets that you
16 were dealing with. If we can go to Government's
17 Exhibit 24.01. Do you recognize this photo?

18 A. I didn't take this photograph personally, but I do
19 recognize it from the case.

20 Q. Is this one of the types of tablets that you
21 performed an analysis on using FTIR?

22 A. Correct.

23 Q. And if we can go to 24.02. Prior testimony also
24 provided to the jury that this was a photo taken in this case.
25 Did you perform analysis on this type of pill, as well?

1 A. Correct.

2 Q. And if we can go to 24.03. Again, prior testimony
3 provided that this was one of the tablets that came in the
4 items received by the FDA lab. Was this one of the types of
5 pills that you performed analysis on?

6 A. Correct.

7 Q. Before utilizing the FTIR equipment did you do
8 anything to verify that it was performing accurately and
9 correctly?

10 A. Yes. Every day before we run any type of samples
11 we have to do what is called a performance verification for
12 each piece of equipment. And for this particular instrument
13 we did that -- or I did that in this case.

14 Q. Previously the jury has heard testimony that
15 several of the items listed came from specific locations
16 significant in this case, specifically the defendant's home on
17 Titian way, the Tonge/Bustin home in South Jordan and blue
18 postal bin, which those items were seized by a postal
19 inspector. They've also heard that some these drug exhibits
20 tested positive for either Fentanyl or Alprazolam. Did you
21 take any specific precautions in dealing with these items?

22 A. Sure. We have a safety procedure in our
23 laboratory, general safety procedure. So we used personal
24 protective equipment, gloves, glasses, laboratory coats. We
25 conduct any type of analysis that we can inside of a

1 ventilation hood. And in the event that we don't have that
2 capability we do have ventilation snorkels where we can
3 actually move those over the piece of equipment that I use,
4 and I can work my hands underneath that snorkel and take the
5 portion of the sample, put it on the aperture, and it provides
6 me with a barrier between the sample and myself. And then if
7 there's anything that becomes airborne that ventilation hood
8 will pick that up.

9 Q. And in regards to the 19 items, did you perform
10 this analysis using FTIR on all at least one pill from all
11 19 items?

12 A. That's correct.

13 Q. And why did you -- or did you perform that test a
14 single time? Multiple times?

15 A. I'm not entirely sure without looking directly at
16 my notes. But I probably looked at it once.

17 Q. Okay. And can you describe what the portion of the
18 pill it is that you actually performed an analysis on?

19 A. Yes. Typically in this case I'll take a tablet and
20 I'll break it in half, and then I'll scrape a portion of the
21 core of the tablet, so the inside of the tablet, onto the
22 aperture of the instrument.

23 Q. And in your analysis did you compare the results of
24 the FTIR of the suspect pills with authentic Oxycodone or
25 Alprazolam pills?

1 A. That's correct.

2 Q. And how do you document your findings after your
3 analysis?

4 A. Well, once we've run the sample we end up with
5 what's called a spectrum, so it's just an XY plot, a graph,
6 and on that graph is a fingerprint of that particular sample.
7 So we compare the fingerprint of the suspect sample to the
8 fingerprint of an authentic sample. And what we would do is
9 provide that data as a printout and then compare those
10 fingerprints to each other to make a determination on if the
11 suspect sample is consist with the authentic or not.

12 Q. I'd like to look at some of that data that you
13 gathered for your analysis. If we can look at Government's
14 Exhibit 24.08. This is an FTIR result that -- or findings
15 that you created; is that right?

16 A. That's correct.

17 Q. It appears that there are four boxes on this
18 exhibit. Can you walk me through each of those boxes and what
19 it is that we're looking at?

20 A. Sure. So if we start in the top left what we have
21 here is the signature of each of the labeled items that I was
22 talking about. So we have an XY plot. On the X axis or
23 horizontal axis that's what wavelength we're looking at. And
24 along the Y axis we're looking at the intensity or absorbance
25 that we're seeing of each wavelength.

1 So if you look at the fingerprint, say, at the top
2 example, Item 14, we get a signature or fingerprint. That
3 fingerprint is consistent with each of the other items in this
4 window here.

5 Q. So if the jury having heard prior testimony that
6 each of the drug exhibits from which these items were taken
7 from came from different locations, can you draw any sort of
8 conclusion based on what we're looking at here?

9 A. The conclusion I would draw is that the infrared
10 signature of each of these tablets from each of these items
11 are consistent with each other.

12 Q. And if we can zoom out and go to the second box.
13 What are we looking at here?

14 A. So the second box here is what is the result of a
15 library search of one of the representative signatures or
16 fingerprints that we were looking at on the previous page. So
17 if you look at the very top it says, search results for the
18 number, Item 14. So what we did was we took the spectrum. We
19 searched it against probably 55- to 60,000 signature
20 fingerprints in our library, and these are the best matches
21 that the computer algorithm determined.

22 Q. So based on what we're looking at here you've got
23 Row 3 and Row 4 that reference microcrystalline cellulose.
24 How likely was it that there was microcrystalline cellulose in
25 Items 14 through 19?

1 A. I didn't document it on here what the ingredients
2 were because the question was just to compare it to authentic.
3 But I do want to point out that based on the data that I'm
4 looking at here, the suspect sample does appear to contained
5 some type of cellulose.

6 Q. Okay. If we can go to Box 3. What is being
7 compared here?

8 A. So in Box 3 we have one of our representative
9 spectra signatures from box Number 1, and we are comparing
10 that fingerprint, that signature, to that of an authentic
11 Alprazolam 2-milligram tablet core that was manufactured by
12 Sandoz.

13 Q. And in your expert opinion, can you draw any
14 conclusions in making the comparison of those two pills, an
15 authentic versus a suspect pill?

16 A. Sure. I can tell if you look at the peak positions
17 along the X axis the signature of the suspect sample is not
18 consistent with that of the authentic.

19 Q. And if we can go to the last box. I believe you've
20 kind of summarized more or less your findings. Is there
21 anything else noted here worth mentioning that you haven't
22 already that you concluded?

23 A. I think this screen here summarizes everything.

24 Q. Okay. Thank you. If we can now go to Government's
25 Exhibit 24.06. Noting a pattern here as to how these are

1 structured we may skip Box 4 because I'm going to anticipating
2 you're going to explain to us what your conclusions are. We
3 can look at Box 1. It appears from this that you're
4 performing an analysis using FTIR for items that are scored as
5 A215s; is that correct?

6 A. That's correct.

7 Q. And tell me the results of your analysis comparing
8 those pills.

9 A. The fingerprint of each of these tablet cores were
10 consistent with each other for each of the items listed in
11 this window here.

12 Q. And if we can go to Box 3. What are we looking at
13 here?

14 A. We're looking at the top representative spectrum
15 from one of those that was shown in window Number 1 compared
16 to the fingerprint of an authentic Oxycodone hydrochloride
17 30 milligram tablet core manufactured by Actavis. And what we
18 can see here as in a similar situation as previously the
19 signature of the suspect sample is not consistent with that of
20 the authentic.

21 Q. And how -- do you have a reason for why or maybe
22 visually is there something that tells you here as to why
23 they're not consistent?

24 A. Yeah. If we look at the different regions down
25 here, we see along the X axis the number 2000. So if we look

1 at everything to the right of that we see a different pattern
2 of these peaks or these absorptions. And based on the
3 differences in each of these peaks we are able to determine
4 that the suspect and authentic are not consistent with each
5 other.

6 We can also see in the authentic Oxycodone we have
7 very sharp peaks around 17 -- between 1500 and 1800 that are
8 characteristics of Oxycodone itself, the active ingredient.
9 Those peaks are not present in the suspect signature.

10 Q. So if we can zoom out. What can you conclude,
11 then, when comparing the suspect pills marked A215 to the
12 authentic Oxycodone pill?

13 A. That the suspect samples were not consistent with
14 the authentic.

15 Q. Were the suspect pills consistent with each other?

16 A. Yes.

17 Q. Okay. If we can move on to Exhibit 24.07. If we
18 can zoom into Box 1. It appears that this is capturing your
19 analysis results for the items provided the FDA lab that had a
20 embossment of an M with a box around it. Is that what that
21 is?

22 A. Correct.

23 Q. And can you explain what we're looking at here?

24 A. Each of the signatures are, fingerprints here were
25 from each of the items that you have described that had or

1 consisted of a sample with an M30 stamp on it. And each of
2 the spectra signatures, fingerprints of each of those tablets
3 are all consistent with each other.

4 Q. And if we can go to Box 3. What are we looking at
5 here?

6 A. We have one representative signature fingerprint
7 from the box Number 1, and it is compared to an authentic
8 Oxycodone 30 milligram core manufactured by Mallinckrodt, and
9 the suspect fingerprint is not consistent with that of the
10 authentic.

11 Q. So if we can zoom out. Is it fair to say that
12 essentially regardless of the location of where these
13 suspecting pills came from all of the suspect pills are
14 consistent with each other?

15 A. Correct. Using this technique, that's correct.

16 Q. But they're inconsistent with authentic Oxycodone?

17 A. That's correct.

18 Q. If all the A215 and M30 suspect Oxycodone pills
19 analyzed were found to be consistent with each other but also
20 found not consistent with authentic Oxycodone pills, based on
21 your training and experience what would you conclude?

22 A. Could you repeat the question? I'm sorry.

23 Q. It might have been a lengthy question. Let me
24 rephrase it.

25 Is it probable based on your findings that all the

1 A215 pills would likely have come from the same source based
2 that they're consistent?

3 A. I would say it's possible. There are other
4 techniques that are more conclusive for that type of
5 conclusion. And I think Mr. Ranieri's technique that he
6 described would probably be the most appropriate to make that
7 type of conclusion.

8 Q. Okay. Thank you.

9 No further questions.

10 THE COURT: Cross-examine?

11 MR. SKORDAS: No questions, Your Honor. Thank you.

12 THE COURT: Thank you. You may step down. And
13 you're excused if you want to be.

14 The government may call its next witness.

15 MR. BURGGRAAF: The United States would call
16 Heather McCauley.

17 THE COURT: Come forward and be sworn, please. Now
18 you can come forward and be sworn.

19 THE CLERK: Please raise your right hand.

20 HEATHER ANNE McCAULEY,
21 called as a witness at the request of Plaintiff,
22 having been first duly sworn, was examined
23 and testified as follows:

24 THE WITNESS: I do.

25 THE CLERK: Please come around to the witness box.

1 Please state your name and spell it for the record.

2 THE WITNESS: Heather Anne McCauley, H-E-A-T-H-E-R
3 A-N-N-E, M-C-C-A-U-L-E-Y.

4 DIRECT EXAMINATION

5 BY MR. BURGGRAAF:

6 Q. Ms. McCauley, thanks for being here today. Can you
7 tell me what your current occupation is and where you're
8 employed?

9 A. Sure. I am currently the director of
10 investigations in Cincinnati, Ohio, in the office of Human
11 Animal Food. And we do inspections for human and animal food
12 manufacturers in the state of Ohio and Kentucky. But before
13 that I was a chemist in the forensic center for almost 26
14 years.

15 Q. And for use of reference I'm going to refer to that
16 as the FDA lab. You say you were employed in there for about
17 20 years?

18 A. I was in the lab for about 26 years. I've been in
19 my current position for about a year.

20 Q. What's your education and background?

21 A. I have a bachelor's of Chemistry -- I'm sorry.
22 Bachelor of Science in Chemistry and in Biology.

23 Q. And when you're employed by the FDA lab what were
24 your job responsibilities?

25 A. I would analyze evidence that was sent to the

1 laboratory for analysis, talk to Office of Criminal
2 Investigation agents, write reports, review reports, write
3 standard operating procedures and review them, maintain
4 instruments, do verification of those instruments and make
5 sure they were running properly.

6 Q. And what training have you received in addition to
7 your education related to your FDA lab position?

8 A. Earlier on in my career I attended a mass spectra
9 interpretation theory class. Also when we get new
10 instrumentations in the laboratory usually we get some type of
11 training from the manufacturer on how to use that equipment,
12 and the FDA itself has various courses that you can take.

13 Q. And do you have any publications related to your
14 job responsibilities that you had at the FDA lab?

15 A. Sure. I've given presentations and publications.
16 I've given presentation at the conference on small molecule
17 science on analyzing and identifying pharmaceuticals; a
18 presentation at the American Academy of Forensic Science on
19 the presence of pharmaceuticals and dietary supplement. I
20 coauthored a paper with Dr. Lanzarotta, The Analysis of
21 Pharmaceuticals, on a piece of equipment that was a
22 combination of fourier-transform infrared and gas
23 chromatography with mass spectrometry.

24 Q. That last one, we're going to talk about that some
25 more.

1 A. Yes.

2 Q. Because you said it you saved me from saying it.

3 Can I abbreviate it from here on out as GCMS?

4 A. Yes.

5 Q. The jury has heard prior testimony about GCMS, and
6 I suspect that they may be somewhat of an expert at the end of
7 the trial themselves. They might put some of you out of work.
8 That being said, can you describe what GCMS is?

9 A. Sure. So again GCMS stands for gas chromatography
10 mass spectrometry. And so the instrument itself for visual
11 purposes, if you can imagine basically a 3-by-3 box that sits
12 on a benchtop. It's pretty unimpressive looking at it from
13 the outside, but the magic happens on the inside. And so the
14 gas chromatography part of that is if you can imagine like a
15 coffee stirrer that's 100-feet long and it's circled upon
16 itself like a coil about 12 inches in diameter. And if you
17 can also imagine that that coffee stirrer had a coating of
18 material on the inside surface of it. So it's open, and stuff
19 can pass through it, but there's a coating on the inside.

20 So what you do is you take your material, whatever
21 you're trying to analyze, and you mix it with some type of a
22 liquid. And you take that liquid, and you pull it up into a
23 syringe and you inject it into the instrument through a port.
24 And that port is about 500 degrees Farenheit. So it turns
25 everything into a gas.

1 And that gas then flows through that coffee
2 stirrer, which is called a column. And that gas interacts or
3 interfaces with the material that's lined on the inside of the
4 coffee stirrer, if you will. And as it interacts with that
5 phase, what's called a phase, it separates out that mixture
6 into its components.

7 So if you imagine like, say, a multivitamin. As
8 those vitamins would be traveling through that column they
9 interact with it at different -- like in different ways that
10 gives it separation. So say a Vitamin C might come out first,
11 Vitamin A might come out next, Vitamin B will come out last.
12 So you get separation in that way. That's what the whole
13 purpose of gas chromatography is is to take a mixture, pass it
14 through a medium and separate it into its components.

15 So once that happens and you have your individual
16 components, they go into what's called the mass spectrometer.
17 And at that point those individual components are hit with a
18 voltage that explodes the molecule into a specific pattern,
19 which is like a fingerprint. And that's how you can identify
20 what it is, because like that Vitamin C explodes the same way
21 every time. It has a specific fingerprint that I can say
22 that's Vitamin C. The same with Vitamin A, et cetera.

23 So then you get a piece of data in your computer
24 that shows a graph with each of those individual components
25 making like a peak, and then you get also what's called the

1 mass spectrum, which is the fingerprint of each one of those
2 peaks.

3 Q. Excellent. So there's essentially two processes
4 that go on within the GCMS instrument.

5 A. Correct.

6 Q. Now I want to backup just a little. Have you
7 testified as an expert before?

8 A. Yes.

9 Q. How many times?

10 A. 8 to 10.

11 Q. Has the court ever made a finding that your process
12 or testing methods were not accurate or correct?

13 A. No.

14 Q. Do you have experience analyzing Oxycodone pills,
15 Alprazolam pills and Fentanyl?

16 A. Yes.

17 Q. So tell me how you became involved in this crime
18 case.

19 A. My supervisor asked me to analyze the evidence that
20 I had submitted to the laboratory.

21 Q. And were you specifically directed to use the GCMS
22 method for analysis?

23 A. Yes.

24 Q. And is the GCMS equipment and tool as well as just
25 the process generally widely accepted in the scientific

1 community?

2 A. Yes. And the technical -- the procedure that we
3 use, I actually wrote that technical procedure and did the
4 validation for it for a laboratory. And that's the general
5 method that we use for GCMS analysis that come into our
6 laboratory. And we have used that procedure on thousands and
7 thousands of samples.

8 Q. Before using this box, the GCMS equipment, do you
9 do anything to verify that it's operating correctly and will
10 give you accurate results?

11 A. Yes. There's different types of verification. The
12 one that's the most important for this analysis specifically
13 is a daily verification where you run what's called a tune.
14 And you're just making sure that the instrument is operating
15 properly in the way that you expect it to on the day of use.
16 We also have different procedures that we do that might be
17 monthly or yearly to make sure that the instrument is in good
18 operation and functioning the way it's supposed to be and well
19 maintained.

20 And in addition to that when I run the samples
21 themselves, the first time that I run them when I don't
22 necessarily know what I have, I run what's called a screen
23 check standard. And it has three known compounds in it that
24 I'm looking to make sure that they're coming out and being
25 separated the way that I mentioned. And in the mass spectrum

1 of them is exactly how I would anticipate them to be. So
2 that's run with that set of analysis to ensure -- another
3 safety to ensure that everything is going the way I would
4 expect it to do that day.

5 Q. In your process when you're analyzing the substance
6 you're actually taking additional steps to ensure the accuracy
7 of the results such as doing multiple tests; is that right?

8 A. Yes. I run the standards in duplicate to make sure
9 that the second time that I analyze it it looks exactly the
10 same as the first that I analyzed it. I also run certified
11 standards.

12 Q. And what are those certified standards?

13 A. Well, it depends on the analysis that you're doing.
14 So in this case the first time that I run the samples is what
15 I call the screen when I'm looking to see what I have. And
16 then once I figure out what I think I have, which at that
17 point I'm calling it a tentative identification. And then
18 I'll run a second time with certified standards.

19 So in this case once I identified that I had the
20 active ingredients of Fentanyl and Alprazolam then I ran
21 certified standards of those two compounds to show that what I
22 see in the sample looks exactly the same as a standard of
23 those materials.

24 Q. And how do you ensure that there's no cross
25 contamination between one test and another or no adulterants

1 when running this analysis?

2 A. Cross contamination between the samples?

3 Q. Between maybe from one test to the next. Does any
4 material remain within the GCMS device between tests?

5 A. Generally no. But we run blank, what's called a
6 blank. So in this case these samples were dissolved into
7 methanol. And then I have a sequence that I run that I set up
8 with each item in what order I'm going to run them in. And I
9 run blanks in-between the samples to ensure that there's
10 nothing that's carrying over that would be showing up that
11 shouldn't be there.

12 Occasionally if something happens that I would
13 question that, I might -- the second time I run stuff I would
14 change the order of the way that I run them so that they're
15 not run in the same order each time. So I do different things
16 to ensure that I don't have that situation that you're
17 describing.

18 Q. In this case did you only perform an analysis on
19 the 19 items that contained different pills or tablets?

20 A. That's correct.

21 Q. And your colleague Mr. Platek on the paper to the
22 left of you there categorized the first 19 items received into
23 three different types of suspect pills or essentially pills
24 with the same scoring on them. In looking at that, does that
25 accurately portray the categories and items that you did your

1 analysis on?

2 A. Yes.

3 Q. And was there a difference in results on any of the
4 items that were scored with A215?

5 A. No. All of the A215s looked the same.

6 Q. And the next one down, Item 6, 8, 9, 10, 12, 13
7 scored with an M box and a 30, the results that you received
8 was there any inconsistency amongst the items?

9 A. No.

10 Q. So each of the items are tested separately;
11 correct?

12 A. Yes.

13 Q. So Items 14 through 19, did you find any
14 inconsistencies in your ultimate results?

15 A. Within the Items 14 through 19 themselves, no,
16 there was no inconsistencies.

17 Q. So let's talk about your results, then. After
18 running the GCMS what did you find for Items 14 through 19?

19 A. Items 14 through 19 were Alprazolam.

20 Q. Okay. And for the items at the top that were the
21 pills that were scored A215, what results did you find?

22 A. Fentanyl.

23 Q. And Items 6, 8, 9, 10, 12, 13 scored with an M box
24 and 30 what results did you find?

25 A. Fentanyl.

1 Q. And you mentioned earlier that you at least run the
2 analysis twice with the GCMS. The second time you ran it did
3 it confirm the tentative results that you got the first time?

4 A. Yes.

5 MR. BURGGRAAF: If I can have one moment, Your
6 Honor?

7 THE COURT: Yes.

8 (Time lapse.)

9 Q. BY MR. BURGGRAAF: I want to ask you, are you
10 familiar with the active ingredient in the authentic A215
11 tablets?

12 A. No; because I don't -- the purpose of my analysis
13 wasn't to address authenticity. The purpose of my analysis
14 was to simply look for any active pharmaceutical ingredients.

15 Q. And in performing your analysis were you asked to
16 find the amount of the active ingredients?

17 A. No.

18 Q. Okay. No further questions.

19 THE COURT: Thank you.

20 Cross-examine?

21 MS. BECKETT: I have no questions for this witness,
22 Your Honor.

23 THE COURT: Thank you.

24 You may step down, and you're excused if you want
25 to be.

1 THE WITNESS: Okay.

2 THE COURT: You may call the next witness.

3 MR. BURGGRAAF: The United States called Dr. Arthur
4 Simone.

5 THE COURT: Come forward and be sworn, please.

6 MR. BURGGRAAF: If I can have a moment, Your Honor.

7 THE COURT: Yes, you may.

8 THE CLERK: Please raise your right hand.

9 ARTHUR SIMONE,

10 called as a witness at the request of Plaintiff,

11 having been first duly sworn, was examined

12 and testified as follows:

13 THE WITNESS: I do.

14 THE CLERK: Please come around to the witness box.

15 Please state your name and spell it for the
16 record.

17 THE WITNESS: Arthur Simone, A-R-T-H-U-R,
18 S-I-M-O-N-E.

19 THE COURT: You may proceed, Mr. Burggraaf.

20 MR. BURGGRAAF: Thank you, Your Honor.

21 DIRECT EXAMINATION

22 BY MR. BURGGRAAF:

23 Q. Thank you, Dr. Simone, for being here this morning.
24 Can you tell me what your current occupation is and
25 where your employed?

1 A. I'm employed after Food and Drug Administration
2 just outside of Washington DC. And I'm senior medical advisor
3 in the office of unapproved drugs and labeling compliance.

4 Q. How long have you been with the FDA?

5 A. 17 years. Almost 17 1/2.

6 Q. And in your current role what are your
7 responsibilities?

8 A. I work in the office of compliance, and our jobs
9 are to make sure that the drugs that are available on the
10 marketplace are those that have been appropriately vetted by
11 FDA, to be sure they're safe and effective and highest quality
12 possible. And those that aren't are removed, and that's what
13 my office does.

14 Q. Let me take you back 17 1/2 years ago. Where did
15 you work before the FDA?

16 A. Prior to FDA I was in private practice. I worked
17 in the Philadelphia area. I was an assistant professor at the
18 University of Pennsylvania for several years and then went on
19 to several other colleges that were there. Hahnemann
20 University, Medical College of Pennsylvania and Drexel
21 University as well as working in private practice.

22 Q. And what type of practice do you have?

23 A. Anesthesia.

24 Q. And what's your education background?

25 A. I started out wanting to be an engineer and got a

1 Bachelor of Science in Engineering Science, and then I went on
2 to Penn State University at that point to get a master and
3 Ph.D. in bioengineering. And my specialty there was gas
4 mixing and aerodynamics and models of the upper airways and
5 the lungs. And after that I went to medical school.

6 Q. And you passed?

7 A. Yes.

8 Q. You may have said it, just so I want to make sure I
9 heard it, do you have a Ph.D.?

10 A. Yes, I do.

11 Q. What's the emphasis for that Ph.D?

12 A. It's bioengineering.

13 Q. Do you provide training instruction to others in
14 your field?

15 A. At FDA?

16 Q. At FDA or elsewhere.

17 A. At FDA I do.

18 Q. What types of training do you provide?

19 A. For my first 14 years at FDA I worked in the office
20 of new drugs where we approved products, new drug products for
21 anesthesia, critical care and in my case also counter
22 terrorism. So I trained people how to do the review work from
23 the clinical side, how to look at the clinical trials that
24 were conducted, how to look at toxicology studies that had
25 been performed, how to reviewed chemistry manufacturing

1 control data in an effort to decide whether the benefit of a
2 new drug outweighed its risk, and also look at the label and
3 to make sure the labeling adequately informed a physician how
4 to use a new drug.

5 Q. You mentioned you're evolved with new drugs
6 applications and teaching others about that process. We'll
7 come back to that. But do you have any publications or have
8 you authored any literature related to your profession?

9 A. I have.

10 Q. What type -- can you give us a couple of examples
11 of your types of publications?

12 A. Sure. One of the big issues that has occurred in
13 recent years was whether anesthesia drugs affect the
14 development of the brains of infants over the last trimester
15 of pregnancy and during the first couple years after birth
16 while the brain is going through a rapid development phase.
17 And we have done in work in that, especially with animals.
18 And in the indication there is a lot of anesthesia drugs can
19 affect the brain adversely and those affects can last
20 throughout life.

21 Q. And have you testified as an expert before?

22 A. I have.

23 Q. How many times?

24 A. Eight times.

25 Q. And has a court ever found that your testimony was

1 inaccurate or not correct?

2 A. No.

3 Q. What training or experience do you have related to
4 Fentanyl and Oxycodone?

5 A. For the first 14 years at FDA I was oftentimes the
6 only anesthesiologist in my division, so I covered all the
7 anesthesia products, and that included all the intravenous
8 formulations of Fentanyl. It's the newer versions of Fentanyl
9 that came on the marketplace, I would be responsible for
10 reviewing those. And for older versions that had been out
11 there for a while I would continue monitoring the safety of
12 those and any changes and indications that the companies would
13 seek.

14 Q. For the jury why don't you explain what is
15 Fentanyl?

16 A. Fentanyl is a potent opioid analgesic. It's a very
17 strong painkiller. It's commonly used in anesthesia and
18 sometimes in the ICU afterward.

19 Q. What did you do to prepare for your testimony
20 today?

21 A. I've had discussions with you about my knowledge
22 regarding Fentanyl and anesthesia in general, and I've just
23 reviewed some of the approvals of products that have been
24 involved in Fentanyl.

25 Q. More generally, what does the FDA consider and

1 approve when an application is submitted as it relates to a
2 controlled substance?

3 A. Can you rephrase that?

4 Q. What's the FDA's role in respect to controlled
5 substances that want to be entered into the marketplace?

6 A. It would actually be treated the same as any other
7 prescription drug product. The company that wanted to market
8 these products would have to come to us and follow all the
9 steps that are normally required to show that whatever its
10 intended use is going to be and whatever the dose is going to
11 be administered that the product is effective. It does what
12 they claim it will do, and that the risks have been well
13 established to the point where we can determine whether the
14 benefits of the drug outweigh the risk or the intended use.

15 Q. So is what you just described part of the new drug
16 application?

17 A. Yes.

18 Q. Are there any other significant parts of that new
19 drug application?

20 A. Yes. So the drug application from very high level
21 includes three things -- or four things, I should say. First
22 is chemistry manufacturing and controls. So that's how the
23 company is going to make the product. It has to be of the
24 highest quality possible to minimize risk. So that includes
25 everything from where they are getting their supplies, their

1 active ingredients, which is the ingredient that does the work
2 of the drug, their inactive ingredients, how they're going to
3 analyze the ingredients when they get them, when you buy from
4 someone who sells them and then you have to also confirm what
5 it says it has, and that it's the purity it's supposed to
6 have.

7 It includes the recipe for how they actually go
8 about making the drugs and equipment they use. It includes
9 all of the specifications for the drug when it's completed and
10 it's in its final format and how they go ahead and test that.
11 It includes having to reserve the products so if there's
12 ever an issue with it they can reanalyze it or give samples.
13 And it includes an inspection to make sure that the facility
14 really has the equipment they claim they have to do all this
15 work. And that the facility is clean enough, if you will,
16 that it's suitable for making drugs, especially injectable
17 drugs. That's one section of the NDA.

18 Q. Thank you. When you were involved with new drug
19 applications did you actually ever go and do the onsite
20 monitoring yourself?

21 A. For inspection, no.

22 Q. Those who did go and do the onsite and monitoring
23 and inspection would they bring back issues or concerns for
24 you to give an opinion?

25 A. Yes. They would if they found something.

1 Q. I want to give you the opportunity to weigh in
2 similarly today. I'd like us to look at Exhibit 13.09,
3 Photo 10.

4 We're looking at photos of the defendant's home on
5 Titian Way back in 2016. And I'd like to walk you through a
6 room for which the jury heard prior testimony about, and
7 similar to what you've done in your profession ask you what
8 concerns or issues may arise were this the location being
9 considered for approval in a new drug application. So do you
10 have anything you could speak to as far as what we're looking
11 at here?

12 A. Just based on a quick glance at the image, one of
13 the concerns is the dust that's on the walls. I'm not sure
14 what all the equipment is and whether it's all intact or not,
15 but there appears to be the one container right in the center
16 of the image where there's some white substance that's in
17 there that's being exposed to the rest of the environment.

18 Q. And why is that -- why is the dust on the wall and
19 the exposed material, why is that of concern?

20 A. There's two concerns. It depends on what the
21 substances are in both places. But you can have the stuff on
22 the wall get into the ingredients going into the drug product
23 and vice versa. Stuff coming out of that container puts
24 people at risk for inhaling it. And if that's what's on the
25 wall it's a substantial amount. And on the other hand, dust

1 from the wall or anywhere else in the room for that matter
2 that gets into that hopper looking device into the medication
3 or the drug can cause harm to whoever takes it.

4 Q. And if we can move to the next photo.

5 Is this indicative of a standard location that
6 would be approved for a pharmaceutical production operation?

7 A. No.

8 Q. And why not?

9 A. It's a very makeshift looking facility. It's not
10 something that appears to be permanent. With the purposes of
11 the Bell jars that are lined up on the tables, I'm not sure --
12 the blockage of the windows with those pillow-like devices and
13 a roll of toilet paper is something that you wouldn't normally
14 see in a facility used by a company like Pfizer. And again,
15 you've got the dust on the walls, the chair. And I'm not sure
16 what those containers are on the shelves and what their
17 intended use is, but I can see they're covered with dust, as
18 well.

19 Q. And just to complete the review of this room if we
20 can go to the next few photos maybe pausing for just a few
21 minutes. I should say seconds. Let's not pause for minutes
22 on each.

23 This is the second pill that the jury heard
24 testimony about, and heard further testimony about powder
25 taken from that hopper being tested positive for Fentanyl.

1 Do you have any additional concerns -- you can hold
2 it there -- did you have any additional concerns based on
3 those additional photos?

4 A. Again, if there's Fentanyl in there because of its
5 potency I would be concerned for the possible exposure for the
6 people in the room either working on the drug or just even in
7 the peripheral of the room, and the fact that it's not
8 covered. Beyond that, the fact that it's just not in a very
9 clean environment. It's not something that at a minimum I'm
10 assuming these are for tablets that are being swallowed as
11 opposed to an injectable form. Even for facilities that make
12 pills the requirements are higher than what would be required
13 for food.

14 So if an inspector were to go in and find roaches
15 in a facility that were making pills or rodent droppings,
16 which they do, they would be told to stop making the products
17 at that facility until the problem was cleared up. And they
18 may be encouraged to recall a product if it had been made and
19 we can demonstrate anything was for risk for patients
20 downstream or something that had already been made.

21 Q. Is that because a facility that produces this type
22 of product, if it's not clean it poses a health hazard for the
23 end user?

24 A. Yes.

25 Q. I want to ask you more generally about the new drug

1 application process. Does the FDA maintain records or a
2 database for all approved new drug applications?

3 A. Yes. There are three databases that we have. Two
4 of them are public, that's drugs at FDA, and what we call the
5 orange book, and they list all of the approved products. And
6 then there's an internal database, which is our Document
7 Archival Reporting and Regulatory Tracking System or DARRTS.
8 The DARRTS system, which is internal, includes a lot of
9 proprietary information and information coming from drug
10 companies required to an approval of their product.

11 Q. Speaking just to the approved applications, did you
12 review the FDA's databases in preparation for your testimony
13 today?

14 A. I did.

15 Q. And in reviewing the databases did you find an
16 approved application for manufacturing or bringing to market
17 any pharmaceuticals including Alprazolam or Fentanyl for any
18 of the following individuals: Alex Tonge, Katie Buston, Mario
19 Noble, Drew Crandall or Jonathan Luke Paz?

20 A. No. I found nothing for them.

21 Q. Similar question, did you find an FDA approved
22 application for the manufacturing or bringing to market any
23 pharmaceuticals including Alprazolam or Fentanyl for Aaron
24 Shamo or Pharma Master?

25 A. I searched for both and found nothing for either.

1 Q. Based on your search of those drug applications,
2 the approved ones, if it was discovered that Mr. Shamo either
3 individually or under a pseudonym of Pharma Master was
4 manufacturing pills scored with an A215 or M enclosed with a
5 box with 30 on the other side, what would you conclude by the
6 fact that he doesn't have an approved application?

7 A. Those are products that have been approved, and
8 he's not listed as one of the manufacturers for them. So
9 there's a Mallinckrodt Oxycodone product and then a Actavis
10 Oxycodone product that meet that description that you're
11 giving, at least what's imprinted on it.

12 There's another database that FDA, we like our
13 databases. It's Electronic Drug Registration and Listing
14 System. So that every company that's marketing a product in
15 the United States has to list their product with us, whether
16 it's an approved product or unapproved or illegally marketed
17 product they still have to list it. And one of the reasons
18 for that is so that we know it's out there in the market. And
19 if there's ever a problem with a product we can trace it back
20 to who made it and see what else they've made and take care of
21 issues that might arise related to that.

22 So if some company was cleaning one of their
23 machines and damaged it or left chemicals in it for the
24 cleaning part that were ending up those chemicals ending up in
25 the final pill form. If someone calls and says, my aunt just

1 died and she was taking these pills and here's the NDC code,
2 we can look it up on the EDRLS or we can look up any other
3 information that should be included in the prescription drug.
4 Find out who made, where they made it. We can send our
5 inspectors there to search. We can find out what other
6 products are made there and might have been contaminated
7 likewise, so it's a public health issue. And none of the
8 names that you mentioned, either the corporate entities or the
9 individuals are registered in EDRLS.

10 Q. Okay.

11 A. And the two products that you just described, the
12 Mallinckrodt and the Actavis Oxycodone products EDRLS when I
13 look to see who's responsible for labeling and manufacturing
14 and packaging, distributing them, none of the entities you
15 just mentioned occur there.

16 Q. FDA is essentially a regulatory agency of the
17 federal government; correct?

18 A. Yes.

19 Q. So if none of the individuals or entities named
20 were found in those databases do you reach a conclusion
21 essentially as part of that regulatory agency about the
22 individual manufacturing of those tablets?

23 A. They would be making an unapproved new drug
24 product.

25 Q. Okay. Sticking to the new drug application

1 process, you yourself were I think you mentioned involved in
2 new drug applications for at least two Fentanyl products; is
3 that correct?

4 A. I was involved with all of the opioid products that
5 were used in the operating room. But involvement can occur in
6 a number of ways. It can be with the initial review of all
7 the clinical studies and everything else which went along with
8 the approval of the first new drug application which allowed
9 the product to be marketed. And then the rest of the life of
10 that product, life in quotes, we follow it for safety issues
11 and make sure that there's no updates to the label, that
12 there's no new problems that have been seen with the drug that
13 we didn't know about before. And sometimes we have to adjust
14 the label accordingly or sometimes we find out there are
15 safety issues that make us take the product off the market
16 altogether.

17 Q. Can you briefly explain your involvement in the
18 product Sublimaze Preservative 3?

19 A. Sublimaze was one of the original Fentanyl products
20 that was approved for injection, and that was approved before
21 my time. So I would have been more of a caretaker for that
22 new drug application and did not do the initial NDA reviewed.

23 Q. So as a caretaker what was your role relating to
24 that product?

25 A. When -- if I can just take one step back. When

1 clinical trials are conducted to approve a drug these are big
2 studies to show that the drugs really does what it's supposed
3 to do with the dose that the company wants to market it for.
4 So they get all the safety information and efficacy
5 information. But these trials are conducted anywhere from a
6 couple hundred to a few thousands people.

7 When it gets marketed it's usually used in hundreds
8 of thousands to millions of people depending on its use.
9 Something like Fentanyl, it's been hundreds of millions over
10 the years. But there you're going to see very rare effects
11 that occur with the product. Something might occur one in a
12 million times or real rare, and some of these can be serious
13 adverse reactions that would warrant relabeling the pill or
14 the products, rather, or sometimes consider taking it off the
15 market. So I was following the safety reports for that.

16 Sometimes the other thing that can happen is a
17 company can come in, and it's not uncommon for them to ask to
18 have their product approved for adults, and they do all the
19 studies in adults. And now it's a requirement that they go
20 back and do studies in children and submit those to us, and we
21 decide whether or not the risks outweigh the benefits or vice
22 versa and can approve the use for products in use for children
23 or a different indication.

24 Q. Okay. So separate NDA, separate product, can you
25 briefly explain your involvement to with Fentanyl Oralete and

1 what its intended purpose of use is?

2 A. Fentanyl Oralete is, it's like a lozenge on a
3 stick. People used to call it a lollipop, but I don't want to
4 use that phrase. But it's something placed between the cheek
5 and the gums and it dissolves quickly, and the Fentanyl is
6 absorbed through the mucous and the gums. It's used for
7 chronic pain and acute severe pain. One of the more common
8 uses was veterans coming back with multiple amputations or
9 pain following exposure to explosive devices.

10 Q. Is it fair to say that that product has more of a
11 time release aspect to it as far as the amount of Fentanyl
12 that is transferred into the bloodstream?

13 A. I can't answer that question. I don't know.

14 Q. Okay. What other forms of Fentanyl are you aware
15 of that FDA has approved for use?

16 A. So there's the injectable type which would normally
17 be given intravenously for sometimes for patients in labor and
18 delivery will have an epidural or other patients that are
19 going into surgery with an epidural or spinal anesthetic, the
20 injectable can be used there.

21 There's a number of sprays that are used either
22 intranasal or sublingual, under the tongue. There's lozenges.
23 There's drug cake. Those are buccal formulations, which again
24 are meant to be absorbed in the lining of the mouth. There's
25 also topical products. There's the Fentanyl patch where it's

1 just absorbed gradually through the skin. And there's
2 iontophoretic products where it's also basically a patch. But
3 there's a battery supply that's there, and it uses electric
4 current to also induce the Fentanyl to go through the skin
5 quickly, more quickly than for a regular patch.

6 Q. And to your knowledge is there any tablet form of
7 Fentanyl that is currently approved by the FDA?

8 A. There is no tablet form that's intended to be
9 swallowed.

10 Q. What about crushed or snorted or smoked?

11 A. No, no and no.

12 Q. Okay. Of the current FDA approved forms of
13 Fentanyl are any of those forms allowed to be used without
14 supervision of a physician?

15 A. No, none of them are.

16 Q. What is your understanding of the definition of a
17 drug under federal law, specifically Title 21 USC 351?

18 A. There's a special legal definition for drug, and
19 the two most common parts are any product that's intended to
20 prevent, treat, mitigate, cure or diagnose disease in man; and
21 the other part would be a nonfood product that's intended to
22 affect the structure or function of the body of man.

23 Q. Does Fentanyl meet that definition?

24 A. It does when it's used for its intended use for the
25 approved products, in other words, to treat pain or prevent

1 pain. And it also meets that definition when it's used
2 recreationally to get high.

3 Q. What about Oxycodone, does it fit that definition,
4 as well?

5 A. Yes.

6 Q. You mentioned you're an anesthesiologist, and
7 you've worked with previously and used Fentanyl; right?

8 A. Yes. On my patients.

9 Q. Now, I'm sorry. I missed that last part, but I'm
10 sure I need to hear it.

11 A. On my patients. I used Fentanyl on my patients.

12 Q. Oh, thank you. That is a important clarification.
13 Let's make sure that the court reporter got that.

14 Just to be clear, though, in your work you haven't
15 used or dealt with Fentanyl in overdose, when someone's come
16 into a hospital or medical setting due to Fentanyl overdose;
17 is that correct?

18 A. Not to treat them. That would usually be an
19 emergency room physician.

20 Q. How about in your experience as an anesthesiologist
21 or otherwise, have you been called upon in the last 20 years
22 to treat somebody with alcohol intoxication or poisoning?

23 A. Not to treat the intoxication itself.

24 Q. Okay.

25 A. Usually my interaction with those people would be

1 if they were in a car accident or something we're going to
2 head to the operating room, I'd be down there to get them
3 ready for that.

4 Q. So tell me and the jury what was the purpose for
5 using Fentanyl in your practice.

6 A. Merely as an analgesic, a pain medicine, and that
7 was both during the surgical procedure or some kind of
8 invasive procedure like a colonoscopy or for labor and
9 delivery, and also to provide pain relief for patients in
10 intensive care or hospital setting afterwards.

11 Q. In your experience have you had the opportunity to
12 observe the effects of Fentanyl on the human body on multiple
13 occasions?

14 A. Yes. In the operating room setting.

15 Q. Are you able to quantity the number of times you've
16 observed the effects of Fentanyl on the human body?

17 A. It would be several thousand.

18 Q. So explain what are the effects that Fentanyl has
19 on the human body?

20 A. Broadly as we give it, in anesthesia we usually
21 titrate our medications to effect. So it's not uncommon to
22 use Fentanyl in another drug product Midazolam prior to
23 surgery just to sedate the patient, make them comfortable. If
24 somebody's coming in and got a broken arm and it's going to be
25 set in the operating room, the Fentanyl would provide the

1 analgesia for something like that.

2 As you start to induce anesthesia, actually put the
3 patient to sleep for the surgical procedure, if you're using
4 Fentanyl to provide some pain relief during the procedure
5 you'll see that they start to breath more slowly, they're
6 breathing more shallow, their pupils will constrict. And
7 eventually they'll stop breathing if you give enough Fentanyl.
8 Usually by that point, though, we've given them another
9 medication like Propofol and make them go off to sleep and
10 unconscious altogether, and we've taken over the airway.

11 Q. What do you mean by taking over the airway?

12 A. So if a patient receives enough opioid as I said
13 they'll start to breath more shallowing and less frequently,
14 and what happens is the carbon dioxide in the blood will build
15 up and the amount of oxygen decreases, and if you don't do
16 something, you don't intervene they'll die. So we manage the
17 airway. We assist with their breathing. Sometimes initially
18 we'll put a mask with oxygen coming through it. It's hooked
19 up to an anesthesia machine which has a ventilator on it. It
20 also has a bag hanging from it so we can gradually squeeze the
21 bag and help move air in and out of the lungs. Once general
22 anesthesia has been induced and the patient is, well, they're
23 unconscious and they're paralyzed, we put a breathing tube
24 into the windpipe, the trachea, and we hook them up to the
25 anesthesia machine later, and we breath for them.

1 Q. Is the slowing of the breathing, kind of what you
2 describe, is it correct to use the term respiratory
3 depression?

4 A. Yes. That would be the technical term for it.

5 Q. In your experience, when you're administering
6 Fentanyl to a patient do you request or monitor the blood
7 Fentanyl levels to determine the amounts of amounts of
8 Fentanyl in the blood?

9 A. No.

10 Q. Why not?

11 A. We -- I guess two reasons. One, we treat the
12 patient, not a number, from a blood level. So whatever the
13 patient needs they get. If I give a little bit and that's
14 adequate, I don't care what the blood level number is. The
15 patient has enough analgesic, you leave them well enough
16 alone. Some people who has a lot more painful condition, car
17 crash, multiple broken bones or cancer patient, then they
18 require a lot more Fentanyl for what a typical level might
19 show for an analgesic effect. So you give them what they
20 need. So you treat the patient, not a number.

21 And the other part to that is that if you are
22 giving a lot and the patient should be more sensitive to the
23 Fentanyl than you would expect you've got everything there to
24 deal with that situation. I can support the airway primarily.

25 Q. So as a physician, as an anesthesiologist, would

1 you leave somebody alone that you've begun to give Fentanyl
2 to?

3 A. No.

4 Q. Do you know the blood Fentanyl -- this may be
5 inherent in your prior answer. But do you know the blood
6 Fentanyl levels that are effective versus potentially toxic?

7 A. No, I don't.

8 Q. Does that go beyond the scope of your practice over
9 the years?

10 A. It goes beyond the scope of the practice. But even
11 in a new drug application it goes beyond the scope of what
12 would be required for that.

13 Q. You mentioned that essentially you don't observe or
14 request the blood Fentanyl levels. Do you -- in providing
15 Fentanyl to a patient do you monitor the dosage?

16 A. We record the dose. So normally what you would do,
17 first of all, the patient has monitors on them. They've got a
18 blood pressure cuff, a pulse oximeter which measures the
19 oxygen levels in the blood. That's what we worry about in
20 terms of what levels. We measure their hear rate. We have a
21 electrocardiograph monitor so we watch the rhythm of the
22 heart. And there's some other monitors following general
23 induction of general anesthesia. So that helps guide us in
24 terms of patient safety. And then just watching the patient's
25 response.

1 If I give Propofol to put someone to sleep, I start
2 out with a low dose. Same thing with Fentanyl, just to see
3 how the patient responds. If I'm not getting an adequate
4 response, I give more. And I keep giving more gradually until
5 I have the right amount. If for some reason I've overshot,
6 then I'm prepared to treat that. When I say I, I mean we as
7 anesthesiologists and nurse anesthetists.

8 Q. What's a typical range of an appropriate dosage
9 that you're using in that setting?

10 A. That varies based on a lot of issues. So it
11 depends on the amount of pain you anticipate for a procedure.
12 Someone coming in for cataract surgery, which is an operation
13 on eye, they may need a very low dose of Fentanyl. Typically
14 they're older people, as well, so they might be a bit more
15 sensitive to Fentanyl. So you might give them 50 micrograms.
16 For most healthy young people a does of 100 micrograms.
17 They'll feel a bit wheezy and willing to go to sleep without
18 much effort. For someone that's coming in for open heart
19 surgery, at least back in the day when we used Fentanyl for
20 that, they could get several milligrams of Fentanyl. The does
21 varies widely depending on the intended use.

22 THE COURT: I want to shift gears on you. What
23 types of substances are usually found in pills that are
24 manufactured and approved by the FDA? Just the general
25 categories of substances.

1 A. I would say there's three things that you'll find
2 in pretty much every drug over the counter and prescription.
3 So you have the active ingredient, and that's the ingredient
4 that does the work of the drugs. It lowers the blood
5 pressure, kills bacteria, open airways and asthmatic. And
6 then you have the inactive ingredient, and those are the
7 things that make the active in a usable form. So if it's a
8 powder you're going to inject you may dissolve it in
9 something. You may want to add a preservative to prevent
10 bacteria from growing in it. If it's a pill you've got this
11 powder, you need to make it something that you can compress
12 into the size and shape that someone can actually take.

13 The other thing that occurs in all of these is
14 nothing is 100-percent pure. And the impurities are something
15 that poses substantial concern to us at FDA. It can propose a
16 significant risk to the patient.

17 Q. How does the FDA regulate the contents of
18 prescription pills?

19 A. So this goes back to what we were talking before
20 about the manufacturing chemistry and MC controls part of the
21 new drug application. So the ingredients that someone buys to
22 make a drug product, they buy it from some firm in China. It
23 comes in. And it's supposed to be salt, it supposed to be 99
24 percent pure. So every ingredient that goes in a drug
25 product, whether it's over the counter or prescriptions drug

1 product, the company is required to test that ingredient when
2 they get it to make sure it really is what it says it's
3 supposed to be and it's as pure as it's supposed to be.

4 When the product is finally made, the finished drug
5 product, the company again has to again retest it and look to
6 make sure that it's within specification. So not only do you
7 have these ingredients, a lot of times the medicines are made
8 by a series of chemical reaction. They just mix the stuff in
9 batches. And oftentimes those reactions don't go all the way.
10 So you still have a little bit of some of the initial
11 ingredients in there. They're not going to help with the drug
12 product be effective. They're not one of the inactive
13 ingredients, so those would be considered impurities, and some
14 of those can be very toxic.

15 Q. If a manufacture, a pill tablet manufacturer, wants
16 to change one of the ingredients, can they just do that on
17 their own and without any grief from the FDA?

18 A. They need to notify us in advance. And sometimes
19 they need to do special testing. So these impurities, things
20 like benzene, which is carcinogenic, stuff like that that you
21 find in a lot of compounds, they have to be within a certain
22 level. If it's a small enough range you have to think it's
23 like 99.8 percent pure, it comes down to dose amounts, they
24 may not have to do anything about it. And when they've tested
25 their product in humans initially, it's that finished product.

1 So you have a sense of the safety with that. It's also tested
2 in animals before it goes to humans.

3 If they tweak the product putting in a new inactive
4 ingredient, they have to reconsider all of these things.
5 Again, does that new active ingredient interact any way with
6 the other ingredients that are there? Does it make the pill
7 less effective? Less safe? Does it introduce some new risk?

8 And just so you know, usually we worry about
9 interactions with active and inactive ingredients. We also
10 worry about reactions of the finished products with the
11 container it's in. Sometimes we found that when pills are put
12 in plastic containers some of the components in that plastic
13 leach into the pills. We even found that pills that are kept
14 in glass containers, which was a surprise to us, some of the
15 components, boron in particular, in glass leaches into the
16 pills. So this almost interaction that goes on over the
17 course of the lifespan of the drug before it expires, and we
18 keep track of all of that. So the small changes or what
19 appear to be small changes have to be vetted by the FDA.

20 Q. Previously you mentioned two manufacturers that
21 create Oxycodone pills, Mallinckrodt and Actavis. Do you know
22 what the active ingredients are in each of their products?

23 A. Oxycodone is the active ingredient.

24 Q. Do you know what quantity of Oxycodone is in each
25 of those pills? Maybe I better specify. The A215 from

1 Actavis and the M30 from Mallinckrodt, do you know what the --

2 A. Those are 30 milligram formulations.

3 Q. In either one of those products should there be any
4 Fentanyl found?

5 A. No.

6 Q. I want to show you -- you mentioned packaging, and
7 I want to show you one of our exhibits. If we can look at
8 Government's Exhibit 7.83.

9 THE COURT: What is it?

10 MR. BURGGRAAF: It's 7.83. Photo 1 and 2. We can
11 stop on Photo 1 for a moment.

12 Q. BY MR. BURGGRAAF: The jury's heard testimony that
13 what's being depicted here is a package that was seized from
14 the Tonge/Bustin porch on November 18, 2016.

15 And, Yvette, would you mind zooming in on the
16 invoice there?

17 This is the invoice that the jury heard testimony
18 about that was included within the package.

19 And, Yvette, if you'll zoom out now.

20 Dr. Simone, based on your experience of the FDA
21 what are the issues that we're looking at here with packaging
22 or other regulatory issues that the FDA deals with?

23 A. I couldn't read all the information on that
24 invoice, just the name of the coffee company. But if this is
25 something that was actually delivered to the end user those

1 plastic bags that's included, those would be considered the
2 immediate container. Per FDA regulations they would have to
3 be determined whether or not there's any interaction with the
4 pills contained in those bags and the bags themselves.
5 There's no labeling on the bags to say what it is, who made
6 it, how to contact someone if there is a problem with it.
7 There's no listing of active and inactive ingredients in it.
8 In short, these would be misbranded drug products.

9 Q. And if we could go to Photo 2. Similarly the jury
10 has heard testimony -- they heard testimony that the pills
11 from that first photo contained Fentanyl. The jury heard
12 testimony this was another package that was picked up from
13 that same night from the same location. Similar issues
14 that -- similar issues is what you described previously?

15 A. Again, this is intended for the end user. There's
16 no labeling on the bags. And again, the concern about
17 interactions between the bags and the product itself.

18 Q. To clarify, so Oxycodone doses, are they most
19 routinely measured in milligrams?

20 A. For the approval oral products, yes, they're
21 milligrams.

22 Q. And how are Fentanyl doses measured?

23 A. They're measured in micrograms.

24 Q. So the metrically challenged, what is the
25 equivalent of micrograms to 1 milligram?

1 A. There are 1,000 micrograms in 1 milligram.

2 Q. And your testimony previously was that
3 100 micrograms, so a 10th of a milligram would be an
4 appropriate Fentanyl dosage to start out with for an adult in
5 your practice?

6 A. Correct. It would can a common dose that would be
7 administered.

8 Q. How does the potency of Fentanyl and Oxycodone
9 compare?

10 A. Fentanyl is multiple times more potent than
11 Oxycodone on a weight-by-weight basis. If you wanted to get a
12 similar analgesic effect for the two products, you would have
13 to give anywhere from 10 to 100 times or maybe even 1,000
14 times more Oxycodone than Fentanyl.

15 MR. BURGGRAAF: If I can have a moment, Your Honor?

16 THE COURT: You may.

17 (Time lapse.)

18 Q. BY MR. BURGGRAAF: Sticking with what you just
19 mentioned as far as the potency, I want to give you some
20 hypotheticals dealing with potency that compare Oxycodone to
21 Fentanyl.

22 If you have an individual who takes 30 milligrams
23 of Oxycodone either orally or by crushing and snorting or
24 smoking it, how likely is it that they will suffer serious
25 adverse health consequences or death as a result?

1 30 milligrams of Oxycodone to clarify.

2 A. That's going to depend on a number of factors. If
3 you're giving it to an infant, if you're giving it to a
4 98-year-old that has a lot of medical problems you're going to
5 have a lot more risk associated with that than a healthy young
6 adult. But for most healthy adults, they would probably
7 tolerate the 30 milligram dose with minimal side effects.

8 Q. And yet to be clear, the FDA has approved an
9 Oxycodone pill in a 30 milligram quantity?

10 A. They have, to treat pain.

11 Q. If an individual takes by comparison 30 milligrams
12 of Fentanyl either orally or by crushing and snorting or
13 smoking it, how likely is it that they will suffer serious
14 adverse health consequences or death as a result?
15 30 milligrams of Fentanyl to qualify.

16 A. It's extremely likely they'll die unless there is
17 some type of intervention beforehand.

18 Q. So those two examples, do those help, then, to
19 accurately depict the difference in potency between
20 30 milligrams of Oxycodone versus 30 milligrams of Fentanyl?

21 A. One way to show it.

22 Q. How about a dosage of only 1 to 4 milligrams of
23 Fentanyl, how likely is it that an individual, an average
24 adult would suffer from adverse health consequences or death?

25 A. Again, in all likelihood if there's no intervention

1 they would die. And if I can just explain my thinking on that
2 a little bit?

3 Q. Yes.

4 A. Back many years ago when I was in practice patients
5 coming in for heart surgery, bypass grafting, valve repairs,
6 they had very fragile hearts. They couldn't tolerate much
7 stress one way or the other. And that includes the stress of
8 inducing anesthesia. But Fentanyl is what we call a very
9 hemometrically dynamic stable drug. It doesn't affect blood
10 pressure, heart rate much. And often time we would give these
11 patients masses doses of Fentanyl. And that would be
12 sufficient for them to undergo the heart procedure up to the
13 point where they were put on heart bypass. And by that I mean
14 the surgeon was able to make an incision down the sternum
15 below the chest, and take a bone saw, cut that bone in half
16 and split the chest open and all without an increase in heart
17 rate or blood pressure. And that would typically take
18 50 micrograms per kilogram in an adult.

19 So a 70 kilogram adult, which was 154 pounds, they
20 would get 3 1/2 milligrams of Fentanyl. An 80 kilogram adult,
21 someone that's 176 pounds, they would get 4 milligrams of
22 Fentanyl. And while we're pushing that drug, it's a massive
23 volume of Fentanyl. They start -- you start to see all the
24 side effects. In particular, the respiratory depression,
25 they stop breathing. And that's normal before we get to the

1 end of the dose. You'll see that after a couple hundred
2 milligrams. But we're ready to intervene that.

3 Q. To qualify, you start seeing those symptoms after a
4 couple hundred milligrams --

5 A. Yes.

6 Q. -- or micrograms?

7 A. I'm sorry. Micrograms.

8 Q. And in that scenario they would die unless there
9 was intervention as far as the breathing aspect of it.

10 A. Correct.

11 Q. So jumping back to that example of maybe 1 to 4
12 milligrams of Fentanyl you stated that there was a likelihood
13 of suffering serious adverse health consequences or death if
14 there wasn't intervention. If that individual was drinking a
15 fifth of vodka or alcohol would that generally change the risk
16 of death or adverse health consequences?

17 A. No. The alcohol is also a respiratory depressant,
18 so it might hasten death. But it would be more the icing on
19 the cake than the cake. The Fentanyl would be the chief part
20 for that.

21 MR. BURGGRAAF: No further questions.

22 THE COURT: Cross-examine?

23 MR. SAM: I have no questions, Your Honor.

24 THE COURT: Thank you. You may step down. And you
25 can be excused.

1 And we'll take a lunch break about 30 minutes.

2 (Whereupon, the jury left the court proceedings.)

3 THE COURT: We'll be in recess for about 30
4 minutes.

5 (Recess.)

6 THE COURT: Are you ready to proceed?

7 MR. GADD: Yes, sir.

8 THE COURT: We'll get the jury and proceed.

9 (Whereupon, the jury returned to the court
10 proceedings.)

11 THE COURT: You may call your next witness.

12 MR. GADD: Thank you, sir. The United States is
13 calls Special Agent Koeneman.

14 THE COURT: Come forward and be sworn, please.

15 ADAM KOENEMAN,
16 called as a witness at the request of Plaintiff,
17 having been first duly sworn, was examined
18 and testified as follows:

19 THE WITNESS: I do.

20 THE CLERK: Please come around to the witness
21 stand.

22 Please state your name and spell it for the record.

23 THE WITNESS: It's Adam, A-D-A-M, Koeneman,
24 K-O-E-N-E-M-A-N.

25 THE COURT: Go ahead, Mr. Gadd.

1 MR. GADD: Thank you.

2 DIRECT EXAMINATION

3 BY MR. GADD:

4 Q. I can hear you well, but do you want to just take
5 that microphone and pull it over? Thanks.

6 A. I don't want to be too loud.

7 Q. Special Agent Koeneman, are you prepared to testify
8 about your part in the investigation of Pharma Master?

9 A. I am.

10 Q. Before we do that let's go over your background and
11 your experience. Can you tell us a little bit about yourself?

12 A. Yes. I was in the Army for about 13 years, in
13 US Army Special Operations. Shortly after that I took a job
14 with ERO, Enforcement Removal Operations. I worked primarily
15 gangs and helped out with narcotics in Dallas, Texas. And
16 then I spent five years in Yuma, Arizona, primarily on
17 narcotics investigations with Homeland Security
18 Investigations. And then I've been in the Salt Lake area for
19 about five years, as well.

20 Q. Let's talk about your involvement in this case now.
21 We've heard plenty of testimony about a package that was
22 seized from Ms. Gleave and Mr. Mausia on November 15th, 2016.
23 You participated in that; correct?

24 A. I did.

25 Q. And after the package was seized it was bagged and

1 booked into evidence?

2 A. It was.

3 Q. And then later transferred to the DEA for testing?

4 A. That's correct.

5 Q. At any point in that experience did any agent to
6 your knowledge promise Ms. Gleave she wouldn't be charged?

7 A. No. That never happens in our agency.

8 Q. Let's talk about a few more people on the chart.
9 Can we look at 17.06 on our screen, as well?

10 Could you identify for the jury, Ms. Elise
11 Christensen?

12 A. She is fifth from the right.

13 Q. Bottom row?

14 A. Yes.

15 Q. That's her; correct?

16 A. Correct.

17 Q. I know she's been mentioned in testimony. But let
18 me ask you, in your investigation did you determine what role,
19 if any, Miss Christensen played?

20 A. I did. Miss Christensen was a package receiver,
21 and she also bought postage and did errands and other kind of
22 administrative tasks for both Ms. Tonge and Miss Bustin as
23 part of the Shamo organization.

24 Q. You interviewed Miss Christensen; correct?

25 A. I did.

1 Q. Did she confess?

2 A. She did.

3 Q. Let's take one more. Could you identify Jordan
4 Vance?

5 A. He is third from the left on the bottom row.

6 Q. And that's him on the screen now?

7 A. That's correct.

8 Q. What was his role in the organization?

9 A. He was I package receiver, as well.

10 Q. If I could take you back to November 22nd, 2016,
11 were you working that day?

12 A. Yes, I was.

13 Q. Did you help on some of the search warrants that
14 were executed that day?

15 A. I did.

16 Q. Where were you assigned to help?

17 A. I went to Ms. Tonge and Miss Bustin's residence.

18 Q. At some point in that day did you and other agents
19 learn about Mr. Noble's alleged involvement?

20 A. We did.

21 Q. What steps were taken to find and interview
22 Mr. Noble?

23 A. Agents went to Mr. Noble's work at eBay and
24 encountered him, and Mr. Noble went with them for an
25 interview.

1 Q. At some point did you end up at the office to
2 review evidence with Mr. Noble?

3 A. Yes.

4 Q. And I should clarify. That same night; correct?

5 A. Yes, sir.

6 Q. Did Mr. Noble give you access to Pharma Master
7 storefront on AlphaBay?

8 A. He did. He gave us his access to the Pharma Master
9 storefront, which was a surrogate access he had.

10 Q. And you went on and looked at it that night; right?

11 A. I did.

12 Q. Did you work pretty late?

13 A. Well into the wee hours of the morning.

14 Q. Why so late?

15 A. We were worried that someone in the organization
16 would delete the data off the Pharma Master page and that we
17 would never see it again.

18 Q. When you were looking with Mr. Noble did you also
19 take screen shots?

20 A. We did. Many.

21 Q. I want to look at a few. Could we look at
22 Exhibit 15.04? Do you recognize this?

23 A. I do.

24 Q. Is this one of those screen shots?

25 A. It is.

1 Q. There's a number of pages here, and I'm going to
2 skip through most. What if we looked, for example, at Page 9.

3 And then, Ms. Laughter, if you could highlight the
4 left half of the screen for us and maybe just the top half of
5 that. So that wasn't very clear. How about the top left
6 quadrant?

7 Do you recognize this as some of the products that
8 were being sold on AlphaBay?

9 A. Yes.

10 Q. So you took these screen shots of AlphaBay
11 generally. You also took screen shots on Pharma Master
12 storefront; correct?

13 A. We did.

14 Q. When you were looking through the Pharma Master
15 page were you able to see orders?

16 A. We were.

17 Q. Did you take screen shots of some of the bigger
18 orders that you found?

19 A. Yes. What we did was we started with the pill
20 orders that were around 50,000 or above, and then we worked
21 our way down to 40,000 and 30,000 and 20,000 down to about
22 5,000 pills at a time.

23 Q. You've had a chance previously to look at
24 Exhibits 15.09 through 15.24. Are those some of the screen
25 shots that you took that you just referenced?

1 A. Yes.

2 Q. I'm not going to drag you through all of them, but
3 I do want to look at just one or two. What if we looked at
4 Exhibit 15.16.

5 And then if we could have the left side maybe the
6 top left quadrant of our screen blown up.

7 Are you able to see from what you're looking at
8 here the user name of the buyer on this order?

9 A. It is Jsquad24. It's on the second line there
10 under Roxy Oxycodone.

11 Q. When you look at this, moving over from where it
12 says Jsquad over to these items on the right of our screen
13 starting with item price, minus commission and net total, what
14 is your understanding of what those three things mean?

15 A. So the item price is what the customer would buy,
16 would purchase the item for; then minus commission goes to
17 AlphaBay, just like eBay or website, they have to take their
18 part; and then the net total is generally what gets sent back
19 to the distributor.

20 Q. If we could come out of this zoom and go a little
21 ways down there's feedback just up a little. Could you read
22 the feedback left by the user who went by Jsquad 24?

23 A. S-O means shout out, to mutha fucking boss of the
24 of darknet PM out here making shit happen and keeping his
25 word, you stay loyal to him and he'll stay loyal to you. Go

1 big or go home. Stop the penny pinching.

2 Q. And then under buyer notes, is that the address to
3 which the buyer wanted his 10,000 pills to be sent?

4 A. Yes.

5 Q. When you were there with Mr. Noble that night and
6 you were taking these screen shots, did you give Mr. Noble any
7 indication as to how you wanted him to go about, you know,
8 showing you things?

9 A. We did. We wanted Mr. Noble to show us exactly how
10 he would log in every day, not do anything differently, and
11 walk us through the process of how he would address customer
12 concerns, how he would communicate with people even so far as
13 to go into cutting, pasting exactly how he did. We wanted
14 just a replication just as if he have was working.

15 Q. So if we zoom out for a moment and look at the
16 entire screen shot, on the right half of our screen here, the
17 second kind of window down, if we zoom down on that I'm going
18 to ask you some questions. Is this something that Mr. Noble
19 pulled up?

20 A. It is.

21 Q. We've heard some testimony about a pgp chain or a
22 key chain. Is this a key chain?

23 A. That's what this is, yes.

24 Q. And looking inside where you see the boxes and some
25 indicators of names and e-mails associated. Do you see those?

1 A. I do.

2 Q. Second from the bottom, do you see the name Pharma
3 Master?

4 A. I do.

5 Q. And then an e-mail Pharma-Master@4life.com?

6 A. Yes.

7 Q. Is this a key pair?

8 A. Yes. A pgp.

9 Q. A pgp pair.

10 A. Pair, yes.

11 Q. Would Mr. Noble use this key pair, the
12 Pharma-Master@4life.com to decrypt messages coming in as part
13 of his work as Pharma Master?

14 A. Yes. He took us through that process.

15 Q. Let's look at just one last one. It's
16 Exhibit 15.25. And then we're going to look, yes, right where
17 you are. Maybe we'll do half and then half.

18 Did Mr. Noble also show you some of the customer
19 service interactions that took place?

20 A. He did.

21 Q. And that's what we're looking at here; correct?

22 A. That's right.

23 Q. This is between Pharma Master and a customer named,
24 who went by the moniker stakbandz; is that right?

25 A. That's correct.

1 Q. Starting at the top could you read this interaction
2 between the customer and Pharma Master?

3 A. Sure. So at the top there stakbandz is using like
4 an insta messaging service within Pharm Master to say that the
5 package never sent.

6 Q. And just to clarify that, that sort of
7 insta messaging service, that's something that AlphaBay
8 provides; correct?

9 A. Yes.

10 Q. And he's communicating with Pharma Master?

11 A. Directly.

12 Q. Okay. I won't cut you off again. Please go ahead.

13 A. So stakbandz says: The package never sent. The
14 second one says: The package never sent. Can I get my money
15 in escrow? This guy never sent them.

16 Pharma Master replies: I am terribly sorry about
17 the delay. The tracking number had to be reissued and we had
18 some stock issues. And he gives like a website to track the
19 tracking. There's a tracking number for the reship. And
20 there's no need for any of your feedback. Thanks for your
21 patience. PM, meaning Pharma Master.

22 Stakbandz replies: I've given you close to a month
23 to correct the error. I've spent a few thousand with you.
24 I've been a good buyer. Am I wrong for expecting good
25 service?

1 Q. And then if we look down.

2 What was Pharma Master's response to those
3 questions about, am I wrong to expect good service?

4 A. So Pharma Master replies: Order was sent.
5 Blacklisted. Bye.

6 And stakbandz says: I want my money in escrow.
7 People are getting sick.

8 Q. When you were going through and taking screen shots
9 late into that evening, why did this stick out to you?

10 A. The fact that -- that was one of the questions we
11 asked Mr. Noble is, had he ever had any feedback that somebody
12 might have got hurt or sick. And he brought up this specific
13 instance. He said he thought he remembered it. And then as
14 we went through some of the feedback we found this one. It
15 was pertinent to us because that indicates to us that some
16 customers may have been getting sick or hurt.

17 Q. If we can change gears entirely now and talk about
18 not online Dark Web evidence but talk about electronic
19 devices. Your agency took the assignment to search electronic
20 devices seized in this investigation; correct?

21 A. That was our assignment, yes.

22 Q. I want to talk about electronic devices associated
23 with two men, Mr. Paz and Mr. Crandall. So let's start first
24 with Mr. Paz. In approximately January of 2017 did police
25 officers execute three warrants of residences where Mr. Paz

1 was known to sometimes reside?

2 A. Yes.

3 Q. Was a taint team used?

4 A. A taint team was used.

5 Q. Will you explain what that means?

6 A. So a taint team is used when we want to separate --
7 so at this time Mr. Paz had been represented by counsel, and
8 once he had been represented by counsel we use a taint team or
9 agents or officers who have nothing to do with our case to
10 search with a search warrant through any of the material that
11 we would like to look at. And what the taint team does is
12 they consult with attorneys to see if there's any privileged
13 information between Mr. Paz and his lawyer. And if there is,
14 they remove that before they give it to the case agents. So
15 we had the taint team look for those things and remove that
16 before we would look at it.

17 Q. And, in fact, in this case they did find some
18 privileged material; correct?

19 A. They did.

20 Q. You've talked about how they review it, and then
21 they'll hand it over to you and the other case agents. Does
22 that happen overnight?

23 A. It does not. It took a number of months.

24 Q. Now there was quite a bit of data at least on the
25 electronic devices; correct?

1 A. Lots of data.

2 Q. Once you did get the electronic devices from those
3 search warrants so case agents could now look at it, was a
4 computer forensic agent from your agency asked to examine
5 those devices?

6 A. Yes.

7 Q. He wrote a report about what he found?

8 A. He did.

9 Q. There was little found that was relevant to the
10 case?

11 A. That's correct.

12 Q. There was one item of note, though; correct?

13 A. Yes.

14 Q. Mr. Paz's iPhone --

15 A. Yes.

16 Q. -- was seized.

17 Mr. Paz at some point began cooperating with
18 agents.

19 A. He did.

20 Q. He gave some interviews?

21 A. Yes.

22 Q. As part of that process did he give you and the
23 other agents guesses as to what his pass code might be on this
24 phone?

25 A. Yes. He gave us multiple variations of a pass code

1 that he thought would work on his phone.

2 Q. Did any of them work?

3 A. None of them worked.

4 Q. As part of that process where he's interviewing
5 with agents did Mr. Paz voluntarily turn over his main
6 computer?

7 A. He did.

8 Q. It was another iMac; correct?

9 A. It was.

10 Q. And he gave you and the other agents permission to
11 search that computer.

12 A. He did.

13 Q. Did it appear -- when you and the other agents were
14 looking at his main computer, did it appear that at least some
15 of his iPhone data was backing up to his iMac?

16 A. Yes. His iPhone, it looked like it was
17 automatically backing up. That was what our impression was.

18 Q. Some of the exhibits pulled from Mr. Paz's computer
19 and they are on our exhibit list, those originally came from a
20 phone; correct?

21 A. That's right. Just like you go home and some
22 people back up their phones to the computer. That's what
23 Mr. Paz did with this particular phone.

24 Q. For all the devices we've talked about were all of
25 the images that agents created of those devices that were

1 seized in those three warrants or for that matter in the
2 entire investigation, were all of those images turned over to
3 the defense?

4 A. Yes. Every bit of every image that we had was
5 turned over to the defense.

6 Q. Nothing was held back?

7 A. Not at all.

8 Q. Let's take just a minute and talk about
9 Mr. Crandall's electronics. Did you hear Mr. Crandall tell
10 the jury that he kept all of his Pharma Master data on a thumb
11 drive?

12 A. Yes.

13 Q. And that he destroyed it when Shamo got arrested?

14 A. Yes. I think in Loas.

15 Q. And that he re-imaged his computer to remove any
16 evidence that might be left on that?

17 A. That's right.

18 Q. And then in approximately May of 2017 did
19 Mr. Crandall and his fiancé fly into Hawaii?

20 A. They did.

21 Q. They were stopped at the airport; correct?

22 A. They were.

23 Q. Their electronics were seized?

24 A. They were seized.

25 Q. And the electronics were previewed at the scene?

1 A. They were.

2 Q. Did you and other agents obtain a search warrant
3 from a federal judge in Hawaii to search those electronics
4 more thoroughly?

5 A. We did.

6 Q. No evidence was found on his devices?

7 A. None.

8 Q. Like before, now with respect to Mr. Crandall's
9 devices, were all of the images of those devices that were
10 created turned over to the defense?

11 A. Absolutely.

12 Q. Nothing was held back?

13 A. Nothing was held back.

14 MR. GADD: Can I have just a moment?

15 (Time lapse).

16 MR. GADD: Nothing further. Thank you.

17 THE COURT: Thank you. You may cross-examine,
18 Miss Beckett.

19 CROSS-EXAMINATION

20 BY MS. BECKETT:

21 A. Good afternoon.

22 Q. Good afternoon, Agent Koeneman. How are you?

23 A. Good.

24 Q. Agent Koeneman, when did you first hear the name
25 Aaron Shamo?

1 A. I couldn't -- I wouldn't know a date.

2 Q. November of 2016?

3 A. It sounds about right.

4 Q. Roughly a few weeks before he was arrested;

5 correct?

6 A. I couldn't tell you a date, like a hard date.

7 Q. But you were aware that he was arrested in

8 November, the end of November 2016; correct?

9 A. Yes.

10 Q. And it would be your testimony that you heard his

11 name sometime around November of 2016 for the first time;

12 correct?

13 A. Yes, that's correct.

14 Q. Were you present for the interview of TJ Edwards

15 that occurred on December 14, 2016?

16 A. I was.

17 Q. Do you remember TJ Edwards telling you that he was

18 approached by Mr. Crandall and asked if he was interested in

19 making some easy money around the end of 2015?

20 A. What I recollect from that is he had a meeting with

21 Sasha Grant, Crandall and Mr. Shamo, and that's how he was

22 recruited.

23 Q. You don't remember him saying that he was initially

24 approached directly by Mr. Crandall?

25 A. That could be correct. We interviewed a lot of

1 people. So if you want I can review that and take a look at
2 it and see if that's correct.

3 Q. That would be great. Just a second.

4 If I may approach, Your Honor?

5 THE COURT: You may.

6 THE WITNESS: Thank you.

7 Q. BY MS. BECKETT: The first half.

8 A. First half?

9 Yeah. It says here that Edwards stated he was
10 introduced to Shamo through a mutual friend, through Crandall,
11 so that's why I understood it to be a meeting that took place.

12 Q. Continue to the bottom of that page, if you will.
13 I believe the beginning of that next paragraph specifically
14 states something.

15 A. Yes. It says here that Edwards stated that he was
16 approached by Mr. Crandall initially.

17 Q. Do you remember Mr. Edwards describing Mr. Shamo
18 and Mr. Crandall as copartners?

19 A. Yeah.

20 Q. And that Mr. Crandall referred to them both as
21 copartners?

22 A. That's in the report, so yes. It's highlighted
23 even.

24 Q. I did try to make that easier to read.

25 A. Thank you.

1 Q. You're welcome.

2 Do you remember Mr. Edwards saying he was paid by
3 Mr. Crandall for the packages that he received?

4 A. I do remember that.

5 Q. Do you remember Mr. Edwards describing that meeting
6 you discussed a second ago with Mr. Crandall and Mr. Shamo and
7 Sasha Grant?

8 A. Do I remember it?

9 Q. Do you remember him describing that?

10 A. I do.

11 Q. Do you remember Mr. Edwards stating that Sasha
12 Grant did not seem surprised by the conversations concerning
13 the alleged drug trafficking?

14 A. Can you repeat that, please?

15 Q. Do you remember Mr. Edwards telling you that Sasha
16 Grant did not seem surprised about the conversations occurring
17 regarding alleged drug trafficking?

18 A. I don't remember that specifically, but I'm
19 guessing it's highlighted in this report?

20 Q. You're welcome to look at that if that will refresh
21 your recollection.

22 A. Thank you. Do you want to help me out and tell me
23 where it's highlighted?

24 Q. Yeah. On Page 3 of 4 in that top paragraph, the
25 third sentence there. It starts there.

1 A. We wrote a lot of these, so....

2 Q. And then halfway down the page there's the sentence
3 that says: Sasha was present throughout.

4 A. Yeah. It says that he -- nor did she seem
5 surprised, that is correct.

6 Q. So it's safe to say that Miss Grant may have had
7 some knowledge of what was actually occurring at that point in
8 time; correct?

9 A. I wouldn't be able to speak to that. That was what
10 was told to me, and I put it down in the report.

11 Q. I believe you stated you were also present for the
12 interview of Elise Christensen that occurred on
13 September 21st, 2016; is that correct?

14 A. Yes.

15 Q. We've already heard significant testimony about who
16 Ms. Christensen is.

17 THE COURT: Slow down a bit.

18 MS. BECKETT: I can do that, Your Honor. I
19 apologize.

20 Q. BY MS. BECKETT: Was Elise Christensen good friends
21 with Alex Tonge and Katie Bustin?

22 A. That's how she described it.

23 Q. Did Miss Christensen ever say that she had
24 personally met Aaron Shamo?

25 A. I don't recall. But it's in the report maybe?

1 Q. Oddly it's not.

2 A. Okay. I don't recall that.

3 Q. She never stated that specifically to you, that she
4 had met Mr. Shamo?

5 A. She never -- I don't recall that. I don't
6 recall -- so your first question was, did she ever state that
7 she had never met, which was confusing a little bit. Sorry.
8 And she -- that's not -- she never not said she had met Aaron
9 Shamo. I mean, that's -- sorry.

10 Q. Would you like me to clarify that one?

11 A. Yeah. A little bit.

12 Q. Did Miss Christensen say that she had personally
13 met Aaron Shamo?

14 A. She did not.

15 Q. Was Miss Christensen under the impression that she
16 was recruited because Ms. Tonge and Miss Bustin wanted to
17 limit their exposure by not receiving packages at their home?

18 A. Did Miss Christensen state that?

19 Q. Yes.

20 A. Let me see. This is a very long report.

21 Q. Page 3 of 5.

22 A. Thank you.

23 Q. Yep. Bottom paragraph.

24 A. Yes, that's correct. They wanted to keep them from
25 their address because they were illegal.

1 Q. Wanted to insulate themselves?

2 A. Yes.

3 Q. Did Elise Christensen since state that it was
4 actually Alex Tonge and Katie Bustin that directed her to
5 download the Telegram app?

6 A. It sounds correct, but I would like to see it in
7 the report to make sure I'm telling the truth here. Do you
8 want to tell me what page that is on?

9 Q. You can just turn to the next page, yes.

10 A. Yep, she did.

11 Q. Were the packages that Miss Christensen received
12 picked up by Katie Bustin and Alex Tonge?

13 A. Generally yes.

14 Q. Was Miss Christensen paid by Katie Bustin and
15 Alex Tonge?

16 A. Yes.

17 Q. Do you know whether Katie Bustin and Alex Tonge
18 financially benefited from recruiting Christensen to receive
19 those packages?

20 A. Did they financially benefit? I guess the greater
21 Shamo organization overall, so they're part of that. So, yes,
22 they did.

23 Q. Was Miss Christensen also friends with Sasha Grant?

24 A. Let me see.

25 Q. Page 5 of 5 of your report.

1 A. We're working well together here.

2 Friends with her on Facebook.

3 Q. I believe it states that she was friends and
4 friends with her on Facebook; correct?

5 A. Yes.

6 Q. Were you also present for the interview of
7 Charmaine Drury on March 17, 2017?

8 A. We're really reaching back here into the archives.
9 Yes. Charmaine Drury, yes.

10 Q. Who is Charmaine Drury?

11 A. She is the mother of Alexandrya Tonge.

12 Q. She received money from Alex Tonge?

13 A. She did.

14 Q. Do you know how much money she received on average
15 from Alex Tonge?

16 A. I don't specifically recall.

17 Q. Would it help you to refer to the bottom of your
18 report to refresh your recollection?

19 A. The underlined portion?

20 Q. That would be correct.

21 A. \$700 per month for rent via bank transfer.

22 Q. For how long?

23 A. From 12 to 18 months. She wasn't very sure.

24 Q. As part of your investigative tasks were you
25 reviewing and tracking the social media of Drew Crandall and

1 Sasha Grant while they were traveling abroad?

2 A. We were.

3 Q. You didn't personally involve yourself in that?

4 A. I did. I just didn't do it exclusively.

5 Q. But that was part of your role?

6 A. It was.

7 Q. Do you remember reviewing a blog titled Drasha
8 Travels?

9 A. We did review that blog.

10 Q. Do you remember seeing a post from April 27th,
11 2017, that outlined the travels of Drew and Sasha over the
12 preceding 18 months?

13 A. I'm familiar with it. And it's right here in my
14 report. So, yes.

15 Q. Do you see the entirety of that posting in your
16 report there?

17 A. No. The posting had photos and all kinds of things
18 in it, so the entirety is not here.

19 Q. Just the text?

20 A. Yes.

21 Q. If you could, I would like you to read through that
22 first section. And it begins at the bottom of that Page 2.

23 A. Of 4?

24 Q. Of 4.

25 A. Uh-huh (affirmative).

1 Q. And goes on to the next page.

2 A. So it says: May to October, move to Auckland, New
3 Zealand. These are just like bullet points. Sasha started
4 working for Ernst & Young. Housesit for six different
5 homeowners.

6 Continue or?

7 Q. Yes, please.

8 A. Drew becomes a stay-at-home dog dad with work on
9 the side. We wait out the winter and enjoy hikes on warm days
10 with our various pups. Realize we were puppy hungry. Drew
11 turns 30 in July. Drew's parents visit, and we have our
12 second family encounter and enjoy every second of it. Save,
13 save, save for upcoming vacations. Sasha is offered
14 sponsorship at work but turns it down for Southeast Asia
15 travel.

16 Q. I'll skip the future portion. I'll skip the
17 portion that says future. And down at the bottom where it
18 says, fun facts?

19 A. Fun facts. We have been to eight countries in two
20 months, 10 countries overall. Since leaving New Zealand we
21 have visited around 29 cities in various countries. We
22 haven't stayed in the same place for more than a month since
23 March 2016. In the last two months we have not stayed more
24 than four days in the same city. We have taken 18 flights,
25 one train, 11 busses, 11 ferries and countless Tuk Tuks. We

1 have taken 155 gigabytes of photos. We would do it all over
2 in a heartbeat.

3 Q. It's probably the reason that you were monitoring
4 that social media is because you wanted to know when
5 Drew Crandall was going to be back in the country?

6 A. That's correct.

7 Q. And it became clear that he was coming back into
8 the country to get married; correct?

9 A. Yes.

10 Q. And you were also present for the interview of
11 Sean Gygi on May 19th, 2017; correct?

12 A. Was I present for that? Oh, yes. We did so many
13 interviews I'm having trouble recalling. But that one I was
14 there for.

15 Q. Understandable.

16 Do you remember Mr. Gygi saying he was, in fact,
17 paid to receive packages by Mr. Crandall?

18 A. Yes.

19 Q. Do you remember Mr. Gygi describing Aaron as not
20 smart enough to learn the process of pill making?

21 A. I don't recall him saying that, but I'm sure it's
22 highlighted here. So, yes. I wrote that in my report, that's
23 correct.

24 Q. Do you remember Mr. Gygi describing Aaron as not
25 having the skills to set up the technical aspects of the

1 operation?

2 A. Yes.

3 Q. Do you remember Mr. Gygi describing Drew Crandall
4 as quite intelligent?

5 A. Yes.

6 Q. Do you remember Mr. Gygi describing Mr. Crandall
7 having computer skills to set up a Dark Web account and
8 storefront?

9 A. Did we go backwards on the report now?

10 Q. Do you remember him saying that?

11 A. I don't remember that specifically, but I was
12 trying to refer to this report.

13 Q. Just the highlighted sections. That one might not
14 be highlighted.

15 A. This is a seven-page report. Excuse me.

16 Yes.

17 Q. Do you remember Mr. Gygi describing that he
18 believed Mr. Crandall and Sasha Grant funded their
19 international travel from the proceeds coming from the sale of
20 illegal narcotics on the Dark Web?

21 A. Yes.

22 Q. Were you also present for the interview of
23 Jordan Vance on June 12th, 2017?

24 A. I was.

25 Q. Do you remember Mr. Vance explaining that he was

1 introduced to Drew Crandall through Sasha Grant?

2 A. Yes.

3 Q. Do you remember Mr. Vance describing that he was
4 actually recruited to receive packages specifically by
5 Mr. Crandall?

6 A. No. I remember Crandall introducing Vance to Shamo
7 and that he was -- he was just approached to have a package
8 sent to him. That's what I remember.

9 Q. Were you present for the interview of Drew Crandall
10 on May 5th, 2017?

11 A. I was.

12 Q. Did he initially tell you that he was funding his
13 international travel through working through IT and tech
14 support?

15 A. Yes. He lied initially.

16 Q. Were there other agents present for that interview?

17 A. Yes, they were.

18 Q. Was Guy Gino one of those agents?

19 A. I don't recall.

20 Q. Do you remember another agent asking Mr. Crandall
21 if he had accessed bitstamp or Bitcoin as late as April of
22 2017?

23 A. I don't recall that, no.

24 Q. Would it refresh your recollection to look at a
25 transcript of that report?

1 A. It would be very helpful.

2 MS. BECKETT: Your Honor if, I may approach?

3 THE COURT: You may.

4 THE WITNESS: It's about 15 pages here.

5 Q. BY MS. BECKETT: Correct. That is not the entirety
6 of the transcript. I'll represent to you it is a 160-page
7 transcript. But if you will look at Page 156 I believe there
8 at the top.

9 A. Okay.

10 Q. Do you see a section in there where Agent Gino
11 inquires as to Mr. Crandall's accessing of Bitcoin?

12 A. Yes, I see it.

13 Q. Did Mr. Crandall deny accessing his Bitcoin?

14 A. Mr. Agent Gino talks a lot. I have to get through
15 this.

16 Q. That is correct.

17 A. Do you know exactly where this is? Do you know
18 what page it's on?

19 Q. What page what is on?

20 A. The question you asked me specifically.

21 Q. Do you see the portion where Agent Gino is asking
22 him about the Bitcoin?

23 A. Yes.

24 Q. Do you see a response from Mr. Crandall denying it
25 on any of those pages?

1 A. I did not know these were front and back, so....

2 Q. Let me get the response to that question. Does
3 Mr. Crandall deny?

4 A. I'll have to review this.

5 So I don't see -- I mean, this is a lot of -- I
6 don't see it here, and that was a very long interview. And
7 often with suspects they initially deny. And then we talk to
8 them longer and get to know them better, and they eventually
9 come around to the truth. So that would not be outside the
10 realm of possibility.

11 Q. I believe you indicated you were also present for
12 some interviews of Mr. Paz; is that correct? There's not a
13 report there for an interview.

14 A. I was going to say I don't think I was, no.

15 MS. BECKETT: Just a second, Your Honor.

16 THE COURT: Yes.

17 MS. BECKETT: I have no further questions, Your
18 Honor.

19 THE COURT: Thank you.

20 Redirect, Mr. Gadd?

21 MR. GADD: Please.

22 REDIRECT EXAMINATION

23 BY MR. GADD:

24 Q. Can you tell me who did it, Mr. Crandall or
25 Mr. Shamo, to the following statements: Hired Mr. Gygi as a

1 full-time runner for his organization.

2 A. That was Aaron Shamo.

3 Q. Paid Mr. Gygi \$2,000 every two weeks to be a
4 full-time runner for his organization.

5 A. That was Mr. Shamo again.

6 Q. Made plans with Mr. Gygi to expand his operation
7 into Colorado.

8 A. Again, Mr. Shamo.

9 Q. On this same topic, let's look at one last exhibit.
10 Could we look at 15.26. That was the video made with
11 Mr. Noble. And if he with could go to 34:42 on the video.
12 And if you could zoom us in on the message there right in the
13 center.

14 Okay. You see that there?

15 A. I do.

16 Q. At this point Mr. Shamo was under arrest; correct?

17 A. Yes, he was.

18 Q. And Mr. Noble was with you.

19 A. He was.

20 Q. But somebody had to tell Pharma Master -- excuse
21 me -- someone had to tell AlphaBay that this account owner got
22 busted today.

23 A. That's correct.

24 Q. Who sent that message?

25 A. Throughout the investigation we uncovered that it

1 was Drew Crandall.

2 Q. And he testified that he sent it, didn't he?

3 A. Correct.

4 Q. So if Mr. Crandall is the mastermind of
5 Pharma Master, if he runs the whole organization and his
6 minion Mr. Shamo has been busted, why is he shutting it all
7 down?

8 A. It's not smart.

9 Q. It wasn't his, was it?

10 A. No. Absolute not.

11 Q. Who's was it?

12 A. It was Mr. Shamo's organization.

13 MR. GADD: No further questions.

14 THE COURT: Thank you.

15 Recross?

16 MS. BECKETT: I have no further questions, Your
17 Honor.

18 THE COURT: Thank you. You may step down and be
19 excused if you want to be.

20 THE WITNESS: Thank you.

21 THE COURT: Do we have any other witnesses today?

22 MR. GADD: That's all of the witnesses for today.

23 THE COURT: And we'll have somebody here at 8:30 in
24 the morning; correct?

25 MR. GADD: Yes, sir.

1 THE COURT: All right. Ladies and gentlemen of the
2 jury, same rules. Have a nice afternoon, and we'll see you at
3 8:30 a.m. And thanks for your work.

4 (Whereupon, the jury left the court proceedings.)

5 THE COURT: We'll see you at 8:30 in the morning.
6 Thank you.

7 (Whereupon, the court proceedings were concluded.)

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1 STATE OF UTAH)

2) ss.

3 COUNTY OF SALT LAKE)

4 I, KELLY BROWN HICKEN, do hereby certify that I am
5 a certified court reporter for the State of Utah;

6 That as such reporter, I attended the hearing of
7 the foregoing matter on August 22, 2019, and thereat reported
8 in Stenotype all of the testimony and proceedings had, and
9 caused said notes to be transcribed into typewriting; and the
10 foregoing pages number from 1404 through 1554 constitute a
11 full, true and correct report of the same.

12 That I am not of kin to any of the parties and have
13 no interest in the outcome of the matter;

14 And hereby set my hand and seal, this ____ day of
15 _____ 2020.

16

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KELLY BROWN HICKEN, CSR, RPR, RMR

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